

# **EPA Jacket 100-1411**

## **Vol.1**

## Harris, Thomas

---

**From:** Marty Monell [Monell.Marty@epamail.epa.gov] on behalf of Workflow Messenger [Workflow\_Messenger@epamail.epa.gov]  
**Sent:** Wednesday, May 08, 2013 7:12 AM  
**To:** Monell, Marty; Harris, Thomas  
**Subject:** Recommendation of Division Directors Negotiated Due Dates has been completed by Marty Monell.

Recommendation of Division Directors Negotiated Due Dates has been completed by Marty Monell.

Author: Thomas Harris  
Chemical: emamectin benzoate  
Form Date: 05/02/2013  
Decision #: D449308

Registration #: 100-RURR

Petition #: ---

Original PRIA Due Date: 09/08/2012  
Previous Negotiated Due Dates: 10/25/2012, 12/20/2012, 03/20/2012, 04/22/2013  
Proposed New PRIA Due Date: 06/07/2013

Click on this link to access this form:

<https://webforms.epa.gov/webforms/webformsadmin.nsf/formOpen?OpenAgent&UNID=21E5D4D2F936219685257B5F006F6523&USERDB=webforms/webformsapp.nsf>

Click on this link to access all your forms:

<https://webforms.epa.gov/webforms/webformsapp.nsf>

**Recommendation of Division Directors  
Negotiated Due Dates**

<b>Decision #:</b> D449308		<b>Registration #:</b> 100-RURR		<b>Petition #:</b> ---	
<input checked="" type="checkbox"/> See page 2 for additional registration entries					
<b>Chemical Name:</b> emamectin benzoate					
<b>Fee Category:</b> R230				<b>PRIA Decision Time Frame:</b> 15 months	
<b>Submitted by:</b> Thomas		Harris		<b>Branch:</b> OCSP/OPP/RD	<b>Date:</b> 05/02/2013
<b>Company:</b> Syngenta Crop Protection					
<b>Original PRIA Due Date:</b> 09/08/2012			<b>Proposed New PRIA Due Date:</b> 06/07/2013		
<b>Previous Negotiated Due Dates:</b> 10/25/2012      12/20/2012      03/20/2012      04/22/2013					
<b>Is the "Fix" in-house?</b>		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> n/a		<b>If not, date "Fix" expected:</b> 04/10/2012	
<b>Negotiated Due Date Reason:</b>					
<b>Additional Data Required</b>		<input type="checkbox"/> Product Chemistry	<input type="checkbox"/> Toxicology	<input type="checkbox"/> Acute Tox	<input type="checkbox"/> Environmental
		<input type="checkbox"/> Efficacy	<input type="checkbox"/> Ecological	<input type="checkbox"/> Residue	<input type="checkbox"/> Other
<b>Data Deficiencies</b>		<input type="checkbox"/> Product Chemistry	<input type="checkbox"/> Acute Tox	<input type="checkbox"/> Efficacy	<input type="checkbox"/> Residue
		<input type="checkbox"/> Environmental	<input type="checkbox"/> Ecological	<input type="checkbox"/> Labeling	<input type="checkbox"/> Other
		<input type="checkbox"/> Toxicology			
		<input type="checkbox"/> Not Submitted			
<b>Late Risk Assessment</b>		<input type="checkbox"/> Human Health <input type="checkbox"/> Ecological			
<b>Interim Consideration</b>		<input type="checkbox"/> Agency Initiated <input type="checkbox"/> Registrant Initiated			
<input type="checkbox"/> CSF	<input type="checkbox"/> Public Process	<input type="checkbox"/> Risk Issues Environmental	<input type="checkbox"/> Risk Issues Human Health		
<input type="checkbox"/> Impurities Review	<input checked="" type="checkbox"/> Label	<input type="checkbox"/> Administrative-FR Notice	<input checked="" type="checkbox"/> Other – Comment Field		
<b>Summary of Deficiency Type(s):</b> <input type="checkbox"/> Not Submitted (N) <input type="checkbox"/> Deficiencies (D)					
<b>Product Chemistry:</b> <input type="checkbox"/> <b>Acute Tox:</b> <input type="checkbox"/> <b>Efficacy:</b> <input type="checkbox"/> <b>Labeling:</b> <input checked="" type="checkbox"/> <b>Ecological Data:</b> <input type="checkbox"/> <b>Other (describe):</b> <input type="checkbox"/>					
<b>Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):</b>					
Phone calls with and emails to Syngenta 3/28/13, 4/10/13, 4/17/13, 4/22/13, 4/30/13, 5/2/13. Initial problems with disagreement on label, then issue with data deficiencies. Two emails (attached) from Syngenta: 4/22/13 requested PRIA extension to 5/3/13 while they corrected label; 5/2/13 requested PRIA extension to 6/7/13 while EPA reviews data.					
<b>"75 Day" Letter sent?</b> <input type="checkbox"/> Yes, Date sent <input type="checkbox"/> No and reason for none? <i>Add comments on page 2</i>					
<b>Rationale for Proposed Due Date:</b> Syngenta wants more time to consider HED required label changes (PPE)					
<b>Registrant notified that this is the last negotiation?</b> <input type="checkbox"/> Yes <input type="checkbox"/> Not Applicable					
<b>Approve:</b> <input checked="" type="checkbox"/>			<b>Disapprove:</b> <input type="checkbox"/>		
<b>If disapproved, action to be taken:</b>					
<b>OD or DOD Signature:</b>				<b>Date:</b>	

Decision #:	Registration #:	Petition #:

**Issue(s) (describe in detail):**

PREVIOUSLY: Originally, two separate actions were submitted within about a month of each other: a new use on cucurbits group 9 R170 and a new use on ornamentals R230. Since HED and EFED decided to run the risk assessments for the two new uses together the PRIA dates were synchronized and have both been negotiated several times since then. [FYI, cucurbits withdrawn 4/22/13 since registrant did not want to accept required PPE label changes.]

**WHY THE DELAY IN SENDING THIS NEGOTIATION FORWARD:**

Sorry for the mess! I had expected a quick end to this action but instead it keeps coming alive again and might now even pass.

During discussions, Syngenta had indicated that as with the cucurbits they were not willing to accept the new PPE requirements on the proposed ornamental label. That killed the action. However, the email from Syngenta on 4/22/13 at 6:55 pm [PRIA due date] clarified that while they were withdrawing the cucurbit actions they would accept the PPE changes on the ornamental label 100-RURR and wished to negotiate the due date to 5/3/13 while they made the label changes. Resurrected, I attempted to accept the label with comments to be able to close the action on 4/22/13 but then realized there were data deficiencies listed in the HED memo. Action was dead again. Since it was now too late to negotiate the due date I did not send the request forward. Bad decision on my part.

I sent the label corrections to Syngenta then spent a couple of days researching the HED data deficiencies. I discovered that all except one had been either been fulfilled, waived, submitted, or final determination of whether study is even needed (and test animal to use) deferred until Registration Review. The one remaining data gap was for a dislodgeable foliar residue study. While HED's default screening DFR assumption allowed the use to pass it was not by a large enough margin to totally waive the DFR requirement. Since we can't issue conditional registrations the action remained dead. The registrant was informed and it was suggested they withdraw the action. Instead, on 5/2/13 they sent information on an existing DFR and discussed how we had previously used this to allow new uses. Resurrected (again), HED is now considering this argument but has said that there is a good possibility that this would resolve the data gap. Negotiation to 6/7/13 requested to officially put this back in action while a final decision is made.

**Comment(s):**



# Audit Trail for

## Recommendation of Division Directors Negotiated Due Dates

**PDF Name:** PRIAv5.pdf

**Form Number:** PRIA

**Document Identifier:** PRIA-13122171247-TH

## Harris,Thomas

---

**From:** tom.parshley@syngenta.com  
**Sent:** Thursday, May 02, 2013 2:18 PM  
**To:** Harris,Thomas  
**Cc:** fred.pearson@syngenta.com; pat.eay@syngenta.com; data.mgmt@syngenta.com; janis.mcfarland@syngenta.com  
**Subject:** RE: emamectin ornamental renegot: make it 1 month (to 6/3)

Tom: Syngenta requests that the PRIA due date to register emamectin benzoate for ornamentals (Enfold, EPA File Symbol 100-RURR) be extended until Friday, June 7, 2013 to allow EPA to address the proposals/rationale Syngenta provided today, May 2, 2013.

Best regards,

Tom Parshley  
Senior Regulatory Product Manager  
Syngenta Crop Protection, LLC

---

**From:** Harris,Thomas [<mailto:harris.thomas@epa.gov>]  
**Sent:** Thursday, May 02, 2013 2:08 PM  
**To:** Parshley Tom USGR  
**Subject:** emamectin ornamental renegot: make it 1 month (to 6/3)

Meredith said to make the negotiation request 1 month. With the furloughs now hitting it's getting tricky to coordinate schedules and we don't want to negotiate again. I still hope we can resolve this in a week or two.

Tom Harris  
EPA/OCSP/OPP/RD  
voice: (703) 308-9423  
fax: (703) 308-0029  
[harris.thomas@epa.gov](mailto:harris.thomas@epa.gov)

---

*This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.*

# \*Personal privacy information\*

**Harris,Thomas**

---

**From:** john.abbott@syngenta.com  
**Sent:** Monday, April 22, 2013 6:55 PM  
**To:** Harris,Thomas; tammy.tyler@syngenta.com  
**Subject:** Re: NEED IMMEDIATELY Monday 4/22/13: FW: Enamectin - cucurbits and ornamentals

Tom

Just now picked up your message. Call my mobile if we need to chat [REDACTED]  
Yes, please withdraw cucurbits for. 100-1270 along with 100-904.

For the ornamentals, we will accept the label changes noted and the PRIA extension request was intended to allow time for the review and approval of the revised label. We will submit the revised label asap to insure you have adequate time. We are interested in having the Agency review the ornamental label as part of the review of the CF-1 mouse rationale and will make the appropriate submission to accomplish this goal.

Hope this makes sense.

Thanks

John

Sent by Blackberry: [REDACTED]

---

**From:** Harris,Thomas <harris.thomas@epa.gov>  
**To:** Abbott John USGR  
**Sent:** Mon Apr 22 18:02:57 2013  
**Subject:** NEED IMMEDIATELY Monday 4/22/13: FW: Enamectin - cucurbits and ornamentals

John,

Hoping this gets to you via Blackberry or something. Two items need immediate attention:

- 1) CUCURBITS: I just sent an email to Tammy about this and called her but I think she has probably gone for the day. I need a confirmation from Syngenta that you want to withdraw the emamectin cucurbit actions for both 100-904 (end use) and 100-1270 (technical). The email below does not mention 100-1270.
- 2) ORNAMENTALS: The negotiation for 100-RURR is another issue but I don't know there's much we can do about that. It is too late to process a negotiation request; that takes at least 1-2 full days. I am assuming from your request for a two week extension that your intention is to adjust the ornamental label to a) drop aerial application so no water soluble packaging is needed, b) add the PPE per HED for mixer/loaders for ground and airblast; and c) require close cabs for airblast application. If that's correct, then we'll have to wind up approving the label after the PRIA date. If that is not your intention then you probably need to withdraw the ornamental application for 100-RURR. Please let me know more info about what you planned to do with the ornamental label in two weeks (actually, one week – I need some time to review and stamp it) OR state in an email that you wish to withdraw the application.

Thanks!

Tom Harris  
EPA/OCSPP/OPP/RD  
voice: (703) 308-9423  
fax: (703) 308-0029  
harris.thomas@epa.gov

**From:** Harris,Thomas  
**Sent:** Monday, April 22, 2013 5:35 PM  
**To:** 'tammy.tyler@syngenta.com'  
**Cc:** tom.parshley@syngenta.com  
**Subject:** RE: Emamectin - cucurbits and ornamentals

Tammy,

There is also a pending action on the technical 100-1270 to add cucurbits. I need an email from you withdrawing that as well.

Tom Harris  
EPA/OCSP/OPP/RD  
voice: (703) 308-9423  
fax: (703) 308-0029  
[harris.thomas@epa.gov](mailto:harris.thomas@epa.gov)

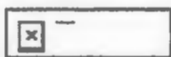
---

**From:** [tammy.tyler@syngenta.com](mailto:tammy.tyler@syngenta.com) [<mailto:tammy.tyler@syngenta.com>]  
**Sent:** Monday, April 22, 2013 5:09 PM  
**To:** Harris,Thomas  
**Cc:** [tom.parshley@syngenta.com](mailto:tom.parshley@syngenta.com)  
**Subject:** Emamectin - cucurbits and ornamentals

Hello Tom,  
Syngenta is withdrawing the current action for 100-904, for the new use of Proclaim Insecticide on cucurbits.  
We would like to request a PRIA extension on 100-RURR for use on ornamentals to May 3, 2013.  
Please contact me if you have any questions.  
Best regards,  
Tammy

---

Tammy Tyler, Ph.D.  
Regulatory Affairs  
Fungicide & Insecticide



410 Swing Rd  
Greensboro, NC  
27409  
USA

phone 336-632-6055  
fax 336-632-5388  
mobile [REDACTED]

---

*This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.*

\*\*\*\*\* ATTACHMENT NOT DELIVERED \*\*\*\*\*

This Email message contained an attachment named  
image001.jpg



which may be a computer program. This attached computer program could contain a computer virus which could cause harm to EPA's computers, network, and data. The attachment has been deleted.

This was done to limit the distribution of computer viruses introduced into the EPA network. EPA is deleting all computer program attachments sent from the Internet into the agency via Email.

If the message sender is known and the attachment was legitimate, you should contact the sender and request that they rename the file name extension and resend the Email with the renamed attachment. After receiving the revised Email, containing the renamed attachment, you can rename the file extension to its correct name.

For further information, please contact the EPA Call Center at (866) 411-4EPA (4372). The TDD number is (866) 489-4900.

\*\*\*\*\* ATTACHMENT NOT DELIVERED \*\*\*\*\*

---

*This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.*



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND  
POLLUTION PREVENTIONMEMORANDUM

Date: 5/8/13

**SUBJECT:** **Emamectin Benzoate.** Status of Deficiencies from the 1/9/13 Revised Human Health Risk Assessment for Proposed Uses on Cucurbits and Outdoor-Grown Plants in Commercial Nursery Production.

PC Code: 122806

Decision No.: 449308

Petition No.: NA

Risk Assessment Type: Single Chemical/Aggregate

TXR No.: NA

MRID No.: NA

DP Barcode: D411607

Registration Nos.: 100-904, 100-RURR

Regulatory Action: Section 3 Registration

Case No.: NA

CAS No.: 155569-91-8

40 CFR: 180.505

**FROM:** Nancy Dodd, Chemist and Risk Assessor *Nancy Dodd*

Nancy Tsaur, Chemist *Nancy Tsaur*Whang Phang, Toxicologist *Whang Phang*

Risk Assessment Branch III (RAB3)

Health Effects Division (HED; 7509P)

**THROUGH:** Christine Olinger, Branch Chief  
RAB3/HED (7509P) *Christine Olinger*

**TO:** Venus Eagle/Thomas Harris, RM #1  
Registration Division (RD; 7505P)

This memo states the current status of each of the data deficiencies in the 1/9/13 human health risk assessment for emamectin benzoate on cucurbits and outdoor-grown plants in commercial nursery production. For the 1/9/13 assessment, the residue chemistry review, dietary assessment, and overall risk assessment were performed by Nancy Dodd. The occupational/residential assessment was performed by Nancy Tsaur. The toxicology assessment was performed by Whang Phang. The drinking water exposure assessment was performed by Tiffany Downen of the Environmental Fate & Effects Division (EFED).

**Data Deficiencies from 1/9/13 Risk Assessment and Current Status***Residue Chemistry Data Deficiency from 1/9/13 Risk Assessment*OPPTS 860.1650 Submittal of Analytical Reference Standards

- The standard for the 8,9-Z isomer of B<sub>1a</sub> (NOA 438376) expired on 3/31/2012. An updated certificate of analysis or a new analytical reference standard must be provided to the EPA National Pesticide Standards Repository.
- Analytical reference standards for MFB<sub>1a</sub> (NOA415692) and 8,9-Z B<sub>1b</sub> are currently unavailable at the Repository. Analytical reference standards must be provided.

*Current Status of Residue Chemistry Data Deficiency re. Analytical Reference Standards*

This deficiency has been resolved. The analytical reference standards have been submitted as requested. The submission was reviewed in D405982 (N. Dodd, 11/20/12). Analytical reference standards for emamectin 8,9-Z isomer of B<sub>1a</sub> and MFB<sub>1a</sub> (NOA415692) were sent to the EPA repository as requested. HED waived the requirement for a separate analytical reference standard for 8,9-Z B<sub>1b</sub> since it is a minor component of the residue as compared to 8,9-Z B<sub>1a</sub>.

*Toxicology Data Deficiencies from 1/9/13 Risk Assessment*870.3465 Subchronic Inhalation

- A subchronic inhalation study is needed. HED determined there was a data gap for a 28-day inhalation study. This study should be performed using the CF-1 mouse.

870.7800 Immunotoxicity

- An immunotoxicity study is needed.

*Current Status of Toxicology Data Deficiencies*

Subchronic Inhalation: EPA will reevaluate the current requirement for the 28-day subchronic inhalation study during Registration Review.

Immunotoxicity: The immunotoxicity study was submitted on 10/24/12 to Registration Division (RD) and turned over to Pesticide Re-evaluation Division (PRD) for tracking/review under Registration Review.

*Occupational Exposure Data Deficiency from 1/9/13 Risk Assessment*

Dislodgeable Foliar Residue (DFR): In accordance with the updated Part 158 data requirements (2007), one or more DFR studies are required when a pesticide has residential or occupational uses that could result in post-application dermal exposure. As part of the recent revision to the

*Health Effects Division's 2012 Standard Operating Procedures for Residential Pesticide Exposure Assessment*, HED analyzed a number of DFR studies and selected a new default value for the fraction of the application rate available to be dislodged after a foliar application ( $F_{AR}$ ). This default value is 25% and is based on an analysis of 19 DFR studies where the  $F_{AR}$  value ranged from 2% to 89%. This value is recommended for use in both residential and occupational postapplication assessments. Of the analyzed DFR studies, the maximum  $F_{AR}$  value seen was 89% or 3.6 times higher than the default residue transfer value. Therefore, the HED has decided that a calculated MOE of approximately 4 times higher than the level of concern (e.g., an MOE > 400 if the LOC = 100) using the default dislodged residue values would provide an adequate margin of safety for any potentially higher residues seen in a chemical-specific DFR study (*Guidance for Requiring/Waiving Turf Transferrable Residue (TTR) and Dislodgeable Foliar Residue (DFR) Studies*, 6/7/2012, Exposure Science Advisory Council). A DFR study is required for emamectin benzoate at this time since the dermal MOE is less than 4 times the LOC based on default values for the fraction of application rate available for transfer after a foliar application.

*Current Status of Occupational Exposure Data Deficiency re. DFR Study*

This deficiency has been resolved. A DFR study conducted with an emulsifiable concentrate (EC) formulation on celery (MRID 44007903) has been submitted and is adequate to satisfy Guideline 875.2100 for the ornamental action.



## Harris, Thomas

---

**From:** tom.parshley@syngenta.com  
**Sent:** Thursday, May 02, 2013 11:18 AM  
**To:** Harris, Thomas  
**Cc:** pat.eay@syngenta.com; fred.pearson@syngenta.com; tammy.tyler@syngenta.com; john.abbott@syngenta.com; timothy.joseph@syngenta.com  
**Subject:** RE: emamectin ornamentals - problem  
**Attachments:** Emamectin Benzoate for Ornamentals - Enfold

Tom: Syngenta risk assessors took a detailed look at the HED documents you provided along with your assessment comments below, and wrote up a brief summary that suggests that perhaps EPA could approve the use on ornamentals after all. This note is attached. Please look over and let's discuss. If needed, I can request another PRIA extension to allow you to further vet this internally if you desire. Just let me know. At this point, Syngenta does not wish to withdraw the action, given what we have determined.

Best regards,

Tom

---

**From:** Harris, Thomas [mailto:harris.thomas@epa.gov]  
**Sent:** Tuesday, April 30, 2013 1:29 PM  
**To:** Parshley Tom USGR  
**Cc:** Eay Pat USGR; Pearson Fred USGR; Tyler Tammy USGR; Abbott John USGR  
**Subject:** emamectin ornamentals - problem

Tom,

We've hit a problem with the emamectin ornamental registration that we cannot get around; we cannot move forward on registering this product. Here's the situation:

### 1) LABEL

There is some good news so let's start with that. Thanks for the quick turnaround on the revised Enfold labels. The label is now fine; no further changes are required.

### 2) DATA

The bad news: This has been staring us all in the face since I sent Syngenta the HED risk assessment back on 1/24/13 but none of us were putting the pieces together to see the problem. On page 8 of the 1/9/13 HED Revised Risk Assessment for emamectin cucurbits and ornamentals there is a section on data deficiencies. The current status of each is in italics after each item.

### OPPTS 860.1550 Proposed Tolerance

A revised Section F must be submitted proposing a tolerance for Vegetable, cucurbit, group 9 at 0.02 ppm.

*[ Done. Cucurbit tolerances were established 3/27/13. ]*

### OPPTS 860.1650 Submittal of Analytical Reference Standards

- The standard for the 8,9-Z isomer of B<sub>1a</sub> (NOA 438376) expired on 3/31/2012. An updated certificate of analysis or a new analytical reference standard must be provided to the EPA National Pesticide Standards Repository.

- Analytical reference standards for MFB<sub>1a</sub> (NOA415692) and 8,9-Z B<sub>1b</sub> are currently

Harris, Thomas

---

**Subject:** Emamectin Benzoate for Ornamentals - Enfold

From: Joseph Timothy USGR  
Sent: Wednesday, May 01, 2013 4:11 PM  
To: Parshley Tom USGR  
Subject: RE: emamectin ornamentals - problem

MRID 440079-03

Tom,

Use of the celery study to justify registration of emamectin on ornamentals should not be a problem.

In January 2002 and again in January 2003 the EPA used the celery study to approve uses on crops despite concerns that data was collected from only one geographical site, that only two applications were made when six are allowed, no tank mix samples were taken, no information on purity was provided and data for an EC was being bridged to a dry granular formulation.

In 2008 EPA did not use the DFR data, but rather used the then default 20% of application rate, in approving uses on tree nuts. The additional reasons cited for not using the DFR study were uncertainty in bridging an EC to a WDG and extrapolation of groundboom to airblast application.

In fact, extrapolation of an SC application to a WDG should engender less uncertainty than extrapolation from an SC to a granular as both SC and WDG are liquid applications. One would expect DFR from a WDG application to be more similar to an SC. It can be agreed that DFR after an airblast application can be expected to be different that after groundboom. However experimentally, DFRs after airblast are lower than those after groundboom.

There should not be a consideration concerning body parts contacted in DFR assumptions. DFR is merely a measure of how much a.i. can be expected to come off of a leaf. The experiment to determine DFR is done by shaking leaf punch samples in a solvent. Body part has no part in the experiment. Body parts are considered in the other factor in the exposure calculation, the transfer coefficient. Transfer coefficients are determined by measuring exposure to all body parts while performing specific tasks, and as long as the TCs from EPA Policy 3 are used, body part is taken into account in the exposure calculation.

Finally, the DFRs found in the celery study showed that an assumption of DFR equal to 25% of application rate is quite conservative. The average DFR used by EPA in 2002 and 2003 is 0.35% of the application rate used in the study ( $0.00591 \mu\text{g}/\text{cm}^2$  after an application at  $0.15 \text{ lb a.i./a} = 0.168 \mu\text{g}/\text{cm}^2$ ). The experimental DFR is two orders of magnitude less than the default.

I would propose that as a conservative estimate EPA could use the DFR from the celery study to justify that a DFR assumption of 25% of application rate may be used and that the additional 4X factor is not required. EPA need not actually use the celery DFRs, simply cite them of supportive of the default. Based on these assumptions exposure due to re-entry into ornamentals should not exceed the level of concern.

Kind Regards

Tim



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

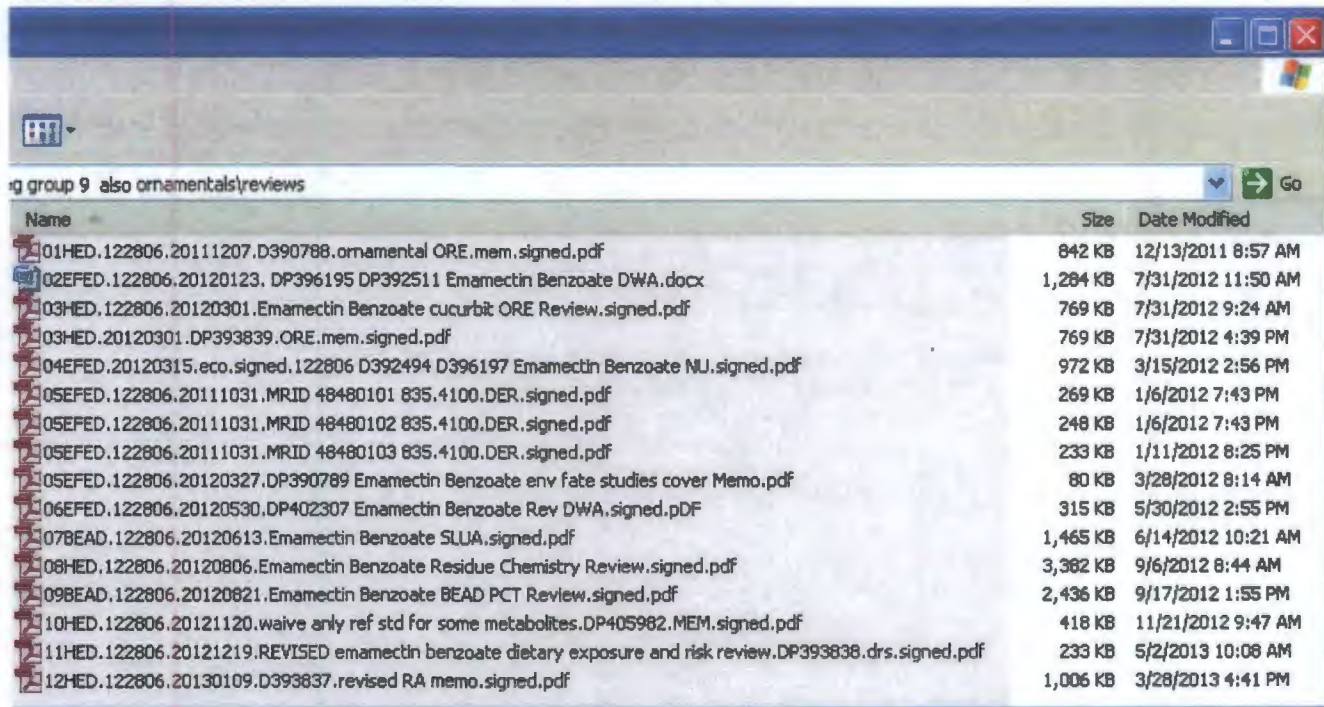
5/2/2013

Tammy Tyler  
Syngenta Crop Protection, Inc.  
PO Box 18300  
Greensboro, NC 27419

re: emamectin new uses on cucurbits group 9 and ornamentals (100-904, 100-1270, 100-RURR, 1E7904)  
copies of EPA reviews

Dear Ms. Tyler:

Enclosed please find a CD with the following reviews for the above actions.



Name	Size	Date Modified
01HED.122806.20111207.D390788.ornamental ORE.mem.signed.pdf	842 KB	12/13/2011 8:57 AM
02EFED.122806.20120123.DP396195 DP392511 Emamectin Benzoate DWA.docx	1,284 KB	7/31/2012 11:50 AM
03HED.122806.20120301.Emamectin Benzoate cucurbit ORE Review.signed.pdf	769 KB	7/31/2012 9:24 AM
03HED.20120301.DP393839.ORE.mem.signed.pdf	769 KB	7/31/2012 4:39 PM
04EFED.20120315.eco.signed.122806 D392494 D396197 Emamectin Benzoate NU.signed.pdf	972 KB	3/15/2012 2:56 PM
05EFED.122806.20111031.MRID 48480101 835.4100.DER.signed.pdf	269 KB	1/6/2012 7:43 PM
05EFED.122806.20111031.MRID 48480102 835.4100.DER.signed.pdf	248 KB	1/6/2012 7:43 PM
05EFED.122806.20111031.MRID 48480103 835.4100.DER.signed.pdf	233 KB	1/11/2012 8:25 PM
05EFED.122806.20120327.DP390789 Emamectin Benzoate env fate studies cover Memo.pdf	80 KB	3/28/2012 8:14 AM
06EFED.122806.20120530.DP402307 Emamectin Benzoate Rev DWA.signed.pdf	315 KB	5/30/2012 2:55 PM
07BEAD.122806.20120613.Emamectin Benzoate SLUA.signed.pdf	1,465 KB	6/14/2012 10:21 AM
08HED.122806.20120806.Emamectin Benzoate Residue Chemistry Review.signed.pdf	3,382 KB	9/6/2012 8:44 AM
09BEAD.122806.20120821.Emamectin Benzoate BEAD PCT Review.signed.pdf	2,436 KB	9/17/2012 1:55 PM
10HED.122806.20121120.waive only ref std for some metabolites.DP405982.MEM.signed.pdf	418 KB	11/21/2012 9:47 AM
11HED.122806.20121219.REVISED emamectin benzoate dietary exposure and risk review.DP393838.drs.signed.pdf	233 KB	5/2/2013 10:08 AM
12HED.122806.20130109.D393837.revised RA memo.signed.pdf	1,006 KB	3/28/2013 4:41 PM

The tolerance for cucurbits crop group 9 was established but the product labels were withdrawn for reasons discussed earlier. I have already sent you some (all?) of the reviews via email but given our email problems I thought it might be best to send you all the reviews on a disc to make sure you had a copy for your records. Note that there is a revised dietary

exposure and risk review dated 12/19/2012 which supersedes a previous 8/29/2012 version.  
If you have any questions please contact me at (703) 308-9423 or [harris.thomas@epa.gov](mailto:harris.thomas@epa.gov).

Sincerely yours,



Thomas C. Harris  
Biologist  
Insecticide-Rodenticide Branch  
Registration Division (7505P)

enclosure

cc: Tom Parshley



Harris,Thomas

---

**From:** Harris,Thomas  
**Sent:** Tuesday, April 30, 2013 1:29 PM  
**To:** 'tom.parshley@syngenta.com'  
**Cc:** pat.eay@syngenta.com; fred.pearson@syngenta.com; tammy.tyler@syngenta.com; john.abbott@syngenta.com  
**Subject:** emamectin ornamentals - problem

Tom,

We've hit a problem with the emamectin ornamental registration that we cannot get around; we cannot move forward on registering this product. Here's the situation:

### **1) LABEL**

There is some good news so let's start with that. Thanks for the quick turnaround on the revised Enfold labels. The label is now fine; no further changes are required.

### **2) DATA**

The bad news: This has been staring us all in the face since I sent Syngenta the HED risk assessment back on 1/24/13 but none of us were putting the pieces together to see the problem. On page 8 of the 1/9/13 HED Revised Risk Assessment for emamectin cucurbits and ornamentals there is a section on data deficiencies. The current status of each is in italics after each item.

#### **OPPTS 860.1550 Proposed Tolerance**

A revised Section F must be submitted proposing a tolerance for Vegetable, cucurbit, group 9 at 0.02 ppm.

*[ Done. Cucurbit tolerances were established 3/27/13. ]*

#### **OPPTS 860.1650 Submittal of Analytical Reference Standards**

- The standard for the 8,9-Z isomer of B<sub>1a</sub> (NOA 438376) expired on 3/31/2012. An updated certificate of analysis or a new analytical reference standard must be provided to the EPA National Pesticide Standards Repository.

- Analytical reference standards for MFB<sub>1a</sub> (NOA415692) and 8,9-Z B<sub>1b</sub> are currently unavailable at the Repository. Analytical reference standards must be provided.

*[ Done. see 11/20/12 NDodd memo; certificate updated, standards for 8,9-A isomer of B<sub>1a</sub> and MFB<sub>1a</sub> submitted; need for 8,9-Z B<sub>1b</sub> standard waived]*

#### **870.3465 Subchronic Inhalation**

A subchronic inhalation study is needed. HED determined there was a data gap for a 28-day inhalation study. This study should be performed using the CF-1 mouse.

*[ See 11/15/11 NDodd et al memo to PRD; During public comment on initial Reg Review documents, Syngenta questioned need for 28-day inhalation and especially for using CF-1 mouse as test animal. HED said Syngenta should submit additional data to support their position and that EPA will reevaluate the current requirement for 28-day inhalation during Reg Review.]*

#### **870.7800 Immunotoxicity**

An immunotoxicity study is needed.

[Submitted 10/24/12 to RD and turned over to PRD for tracking/review under Reg Review. Currently in review by HED. Submission satisfies requirement for the moment (study is assumed to be acceptable). ]

### **Dislodgeable Foliar Residue (DFR)**

In accordance with the updated Part 158 data requirements (2007), one or more DFR studies are required when a pesticide has residential or occupational uses that could result in post-application dermal exposure. As part of the recent revision to the *Health Effects Division's 2012 Standard Operating Procedures for Residential Pesticide Exposure Assessment*, HED analyzed a number of DFR studies and selected a new default value for the fraction of the application rate available to be dislodged after a foliar application ( $F_{AR}$ ). This default value is 25% and is based on an analysis of 19 DFR studies where the  $F_{AR}$  value ranged from 2% to 89%. This value is recommended for use in both residential and occupational postapplication assessments. Of the analyzed DFR studies, the maximum  $F_{AR}$  value seen was 89% or 3.6 times higher than the default residue transfer value. Therefore, the HED has decided that a calculated MOE of approximately 4 times higher than the level of concern (e.g., an MOE > 400 if the LOC = 100) using the default dislodged residue values would provide an adequate margin of safety for any potentially higher residues seen in a chemical-specific DFR study (*Guidance for Requiring/Waiving Turf Transferrable Residue (TTR) and Dislodgeable Foliar Residue (DFR) Studies*, 6/7/2012, Exposure Science Advisory Council). A DFR study is required for emamectin benzoate at this time since the dermal MOE is less than 4 times the LOC based on default values for the fraction of application rate available for transfer after a foliar application. [Table D7 on page 59 gives short- and intermediate-term post application exposures and risk estimates.]

*[DFR study has been required since 2007 (before the ornamental new use was submitted). If EPA does not have a DFR study then The Agency uses screening level assumptions (eg. 25% DFR). For emamectin ornamentals the MOE for dermal post-app is greater than LOC for ornamentals short term LOC and therefore passes. However, since the MOE is not at least 4X larger than the LOC, the DFR study requirement still stands. ]*

### **3) PROBLEM**

The Agency was recently sued for our use of conditional registrations under FIFRA 3(c)(7) to grant registrations; the suit has not yet been resolved. However, the Agency has adopted a policy of not granting any conditional registrations except in rare situations. Registrations and amendments will only be unconditionally granted under FIFRA 3(c)(5).

In the list of data deficiencies above for emamectin ornamentals there are two outstanding studies: a) 28-day inhalation and b) dislodgeable foliar residue. It could be argued that the 28-day inhalation has been temporarily deferred since the Agency said they would revisit the requirement (and the test animal) during Registration Review. But even setting that study aside we are still left with the 2007 requirement for a DFR study. While the Agency's default assumptions resulted in a dermal MOE that is greater than the LOC and therefore acceptable, the ratio was not great enough to waive the requirement for the DFR study.

Therefore, since there is an outstanding data requirement (possibly two) we cannot grant a 3(c)(5) unconditional registration for the ornamental product and thus cannot move forward.

### **4) ACTION ITEMS**

Syngenta - Your only option is to withdraw the action, run the DFR study, and resubmit the ornamental new use. Since we are operating under your request for a 5/3/13 negotiated due date I need a response from you by 5:00 pm Thursday 5/2/13.

Agency – EPA needs to clarify the status of the 28-day inhalation requirement with regard to an ornamental product resubmission.

Tom Harris  
EPA/OCSP/OPP/RD  
voice: (703) 308-9423  
fax: (703) 308-0029  
[harris.thomas@epa.gov](mailto:harris.thomas@epa.gov)

## Harris, Thomas

---

**From:** Olinger, Christine  
**Sent:** Tuesday, April 30, 2013 11:46 AM  
**To:** Harris, Thomas  
**Cc:** Tsaur, Nancy; Dodd, Nancy; Laws, Meredith; Hebert, John; Phang, Whang  
**Subject:** RE: emamectin ornamentals - clarification statement needed

Tom, Meredith, John –

Regarding the deficiencies:

- The analytical standard has been submitted. This deficiency does not apply to the ornamentals, since this requirement applies only to uses with tolerances.
- The immunotoxicity study has been submitted and is under review, so this is not considered a deficiency.
- The subchronic inhalation study applies to all registrations, including the ornamental use, and has not been submitted.
- The DFR study applies to most registrations, and applies to the ornamental use as well.

Please let us know if you need additional information.

Chris Olinger

~~~~~  
Christine Olinger, Chief  
Risk Assessment Branch III  
US National Coordinator for the OECD Test Guideline Program  
US Environmental Protection Agency  
Office of Pesticide Programs/Health Effects Division  
1200 Pennsylvania Ave. NW (7509P)  
Washington DC 20460  
Deliveries: 2777 Crystal Drive (Room 10751); Arlington, VA 22202  
Phone: 703-305-5406  
Fax: 703-305-5147

Visit: [epa.gov/pesticides](http://epa.gov/pesticides)

---

**From:** Harris, Thomas  
**Sent:** Monday, April 29, 2013 6:17 PM  
**To:** Olinger, Christine  
**Cc:** Tsaur, Nancy; Dodd, Nancy; Laws, Meredith; Hebert, John  
**Subject:** emamectin ornamentals - clarification statement needed

Chris,

I was going to accept the emamectin ornamental new use label last week when I ran into a snag. While the risk assessment passes there are a number of data deficiencies listed. Given the current policy on conditional registrations that presents a problem.

Things got more interesting when I looked into each of the data deficiencies. Here they are from the 1/9/13 Revised HED Risk Assessment for emamectin on cucurbits and ornamentals along with what I tracked down on each in *italics*. Copies of cited reviews are attached.



Thanks for your help.

## **ACTION SOUGHT**

Given information below, could HED please write a short memo stating current status of the emamectin deficiencies relative to the ornamental new use. State whether there are still outstanding deficiencies that would prevent registration of new use on ornamentals. This will be used along with 1/9/13 HED Revised Risk Assessment to decide if we can move forward with this action or not.

## **STATUS OF EMAMECTIN DATA DEFICIENCIES RE: ORNAMENTAL NEW USE (from 1/9/13 RA)**

### **OPPTS 860.1650 Submittal of Analytical Reference Standards**

- The standard for the 8,9-Z isomer of B1a (NOA 438376) expired on 3/31/2012. An updated certificate of analysis or a new analytical reference standard must be provided to the EPA National Pesticide Standards Repository.
- Analytical reference standards for MFB1a (NOA415692) and 8,9-Z B1b are currently unavailable at the Repository. Analytical reference standards must be provided.  
*[ see 11/20/12 NDodd memo; certificate updated, standards for 8,9-A isomer of B1a and MFB1a submitted; need for 8,9-Z B1b standard waived]*

### **870.3465 Subchronic Inhalation**

A subchronic inhalation study is needed. HED determined there was a data gap for a 28-day inhalation study. This study should be performed using the CF-1 mouse.

*[ see 11/15/11 NDodd et al memo to PRD; During public comment on initial Reg Review documents, Syngenta questioned need for 28-day inhalation and especially for using CF-1 mouse as test animal. HED said Syngenta should submit additional data to support their position and that EPA will reevaluate the current requirement for 28-day inhalation during Reg Review.]*

### **870.7800 Immunotoxicity**

An immunotoxicity study is needed.

*[submitted 10/24/12 to RD but turned over to PRD for tracking/review under Reg Review]*

### **Dislodgeable Foliar Residue (DFR)**

In accordance with the updated Part 158 data requirements

(2007), one or more DFR studies are required when a pesticide has residential or occupational uses that could result in post-application dermal exposure. As part of the recent revision to the *Health Effects Division's 2012 Standard Operating Procedures for Residential Pesticide Exposure Assessment*, HED analyzed a number of DFR studies and selected a new default value for the fraction of the application rate available to be dislodged after a foliar application (FAR). This default value is 25% and is based on an analysis of 19 DFR studies where the FAR value ranged from 2% to 89%. This value is recommended for use in both residential and occupational postapplication assessments. Of the analyzed DFR studies, the maximum FAR value seen was 89% or 3.6 times higher than the default residue transfer value. Therefore, the HED has decided that a calculated MOE of approximately 4 times higher than the level of concern (e.g., an MOE > 400 if the LOC = 100) using the default dislodged residue values would provide an adequate margin of safety for any potentially higher residues seen in a chemical-specific DFR study (*Guidance for Requiring/Waiving Turf Transferrable Residue (TTR) and Dislodgeable Foliar Residue (DFR) Studies*. 6/7/2012, Exposure Science Advisory Council). A DFR study is required for emamectin benzoate at this time since the dermal MOE is less than 4 times the LOC

based on default values for the fraction of application rate available for transfer after a foliar application.

*[Using screening assumptions (eg. 25% DFR) the MOE for dermal post-app is greater than LOC for ornamentals short term LOC and therefore passes. However, since MOE is not 4X larger than LOC it triggers need for DFR study. How is this handled given current policy on conditional registrations? This will be discussed with OGC as well.]*

Tom Harris  
EPA/OCSPP/OPP/RD  
voice: (703) 308-9423  
fax: (703) 308-0029  
[harris.thomas@epa.gov](mailto:harris.thomas@epa.gov)





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND  
POLLUTION PREVENTION

**MEMORANDUM**

**Date:** 11/15/11

**SUBJECT: Emamectin Benzoate:** Response to Public Comments on the Human Health Assessment Scoping Document in Support of Registration Review (Docket ID EPA-HQ-OPP-2011-0483).

**PC Code:** 122806

**Decision No.:** 457031

**Petition No.:** NA

**Risk Assessment Type:** NA

**TXR No.:** NA

**MRID No.:** NA

**DP Barcode:** D395695

**Registration No.:** NA

**Regulatory Action:** Registration Review

**Case No.:** 7607-1

**CAS Nos.:** emamectin: 19791-41-2

(formerly 123997-28-4 and 137335-79-6);  
emamectin benzoate: 155569-91-8 (formerly  
137512-74-4)

**40 CFR:** 180.505

**FROM:** Nancy Dodd, Chemist/Risk Assessor  
Whang Phang, Senior Toxicologist  
Risk Assessment Branch III (RAB3)  
Health Effects Division (HED) (7509P)  
Office of Pesticide Programs (OPP)

**THRU:** Paula Deschamp, Branch Chief  
Risk Assessment Branch III  
HED/OPP (7509P)

**TO:** Mary Manibusan/Katherine St. Clair, RM#51  
Risk Management and Implementation Branch II (RMIBII)  
Pesticide Re-Evaluation Division (PRD)/OPP (7508P)

Pesticide Re-evaluation Division has requested HED's response to public comments received on the initial Registration Review Documents for emamectin benzoate (Registration Review Docket EPA-HQ-OPP-2011-0483). Comments and HED's responses are presented below.

**Syngenta Crop Protection Comment:**

Syngenta provided extensive comments regarding HED's standing requirement for a 28-day inhalation toxicity study using the CF-1 mouse (-/- P-glycoprotein homozygous phenotype), and further proposed that CF-1 mouse is the inappropriate test model for assessment of human health risk via any route of exposure. Syngenta also indicated they have additional information which they plan to submit to the Agency to support their argument that the CF-1 mouse is not the appropriate species for human health risk assessment. These data include: 1) results of a preliminary inhalation toxicity range finding study with emamectin in the CF-1 mouse (-/- P-gp); 2) a comparison of the pharmacokinetic profile of emamectin in phenotyped CF-1 (+/+ and -/-) to that of abamectin and ivermectin; 3) a comparison of emamectin, abamectin and ivermectin *in vitro* mouse and human gene expression in neuroblastoma cells; 4) a comparison of emamectin neurotoxicity data following inhalation exposure in both P-gp competent and deficient mice with abamectin/ivermectin toxicity following acute oral exposure.

**Response:**

Syngenta should submit the additional data believed to support their position regarding use of the CF-1 mouse for human health risk assessment. Upon receipt, HED will review and consider both the requirement for an inhalation toxicity study in the CF-1 mouse and the appropriate test model to establish points of departure and uncertainty factors for human health risk assessment.

**Physicians Committee for Responsible Medicine Comment:**

The PCRM expressed concerns for animal welfare if mice are used as the test species in a nose-only 28-day inhalation toxicity study noting that a whole body exposure protocol would reduce pain and suffering.

**Response:**

The current requirement for a 28-day inhalation toxicity study in the CF-1 mouse will be reevaluated during Registration Review.

Harris, Thomas

copy FYI  
trades (under 100-904)

**From:** Harris, Thomas  
**Sent:** Monday, April 29, 2013 1:40 PM  
**To:** tammy.tyler@syngenta.com  
**Subject:** FW: Analytical reference standards for emamectin benzoate are needed.  
**Attachments:** Ltr to EPA emamectin - analy ref standards 10-12-12.pdf; HED.122806.20121120.waive only ref std for some metabolites.DP405982.MEM.pdf

Tammy,

Cleaning up some paperwork and not sure if I ever sent the final EPA decision memo to Syngenta.

For emamectin, HED had noted that some material for the analytical reference standards needed updating. Carolyn took care of this but submitted a waiver request for submission of analytical reference standards for two metabolites (attached along with email history). The waiver was granted (copy of EPA review is attached). No further action required by Syngenta at this time.

Tom Harris  
EPA/OCSPP/OPP/RD  
voice: (703) 308-9423  
fax: (703) 308-0029  
harris.thomas@epa.gov

---

**From:** Thomas Harris [mailto:harris.thomas@epamail.epa.gov]  
**Sent:** Monday, April 29, 2013 1:35 PM  
**To:** Harris, Thomas  
**Subject:** Fw: Analytical reference standards for emamectin benzoate are needed.

Tom Harris  
EPA/OCSPP/OPP/RD/IRB  
voice: (703) 308-9423  
fax: (703) 308-0029  
[harris.thomas@epa.gov](mailto:harris.thomas@epa.gov)  
visit <http://www.epa.gov/pesticides>

----- Forwarded by Thomas Harris/DC/USEPA/US on 04/29/2013 01:35 PM -----

From: <carolyn.brinkley@syngenta.com>  
To: Thomas Harris/DC/USEPA/US@EPA  
Date: 10/12/2012 02:51 PM  
Subject: RE: Analytical reference standards for emamectin benzoate are needed.

---

*e-file: emamectin tolerance - (IR-4) cucurbits/ EPA requirement re: analytical ref standards at EPA Repository*



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

**MEMORANDUM**

**Date:** 11/20/12

**SUBJECT:** Emamectin Benzoate. Analytical Reference Standards.

**PC Code:** 122806

**Decision No.:** 470695

**Petition Nos.:** 1E7904

**Risk Assessment Type:** NA

**TXR No.:** NA

**MRID Nos.:** NA

**DP Barcode:** D405982

**Registration No.:** 100-904

**Regulatory Action:** Section 3 Registration

**Case No.:** NA

**CAS No.:** 155569-91-8

**40 CFR:** 180.505

**FROM:** Nancy Dodd, Chemist *Nancy Dodd*  
Risk Assessment Branch III (RAB3)  
Health Effects Division (HED) (7509P)

**THROUGH:** Leung Cheng, Senior Chemist *Leung Cheng*  
RAB3/HED (7509P)

**TO:** John Hebert/Thomas Harris, RM #07  
Registration Division (RD) (7505P)

**I. CONCLUSIONS/RECOMMENDATIONS**

Analytical reference standards for emamectin 8,9-Z isomer of B<sub>1a</sub> and MFB<sub>1a</sub> (NOA415692) have been sent to the EPA repository as requested.

HED waives the requirement for a separate analytical reference standard for 8,9-Z B<sub>1b</sub> since it is a minor component of the residue as compared to 8,9-Z B<sub>1a</sub>.

## II. ACTION REQUESTED

The petitioner was requested to supply the following analytical reference standards:

- The standard for emamectin 8,9-Z isomer of B<sub>1a</sub> (NOA 438376) expired on 3/31/2012. An updated certificate of analysis or a new analytical reference standard must be provided to the EPA National Pesticide Standards Repository.
- Analytical reference standards for MFB<sub>1a</sub> (NOA415692) and 8,9-Z B<sub>1b</sub> are currently unavailable at the Repository. Analytical reference standards must be provided.

## III. BACKGROUND

Analytical reference standards were requested in connection with PP#1E7904 on cucurbits (D392510, N. Dodd, 8/6/12). At that time, analytical reference standards for emamectin benzoate and its regulated metabolites were available at the EPA National Pesticide Standards Repository (personal communication with T. Cole, ACB, 12/20/11) as follow: emamectin benzoate, mix of B<sub>1a</sub> and B<sub>1b</sub> (expiration 2/1/13), emamectin 8,9-Z isomer of B<sub>1a</sub> (NOA 438376; expiration 3/31/12), emamectin desmethyl (AB<sub>1a</sub>; NOA 438309; expiration 5/31/13), and emamectin des-*N*-methyl *N*-formyl B<sub>1a</sub> (FAB<sub>1a</sub>; NOA 415693; expiration 2/28/13).

## IV. RESULTS/DISCUSSION

The petitioner has responded by sending analytical reference standards to the EPA repository for emamectin 8,9-Z isomer of B<sub>1a</sub> and MFB<sub>1a</sub> (NOA415692). The petitioner has requested a waiver of the requirement for the 8,9-Z isomer of B<sub>1b</sub>. The petitioner indicates that 8,9-Z B<sub>1b</sub> has never been isolated as an analytical reference standard since it is a minor component of the residue.





Carolyn F. Brinkley  
Sr. Regulatory Product Manager/NAFTA  
Phone: (336) 632-2838  
Fax: (336) 632-5688  
e-mail: [carolyn.brinkley@syngenta.com](mailto:carolyn.brinkley@syngenta.com)

Syngenta Crop Protection, LLC  
P.O. Box 18300  
Greensboro, NC 27419-8300  
Phone: (336) 632-6000  
[www.syngenta.com](http://www.syngenta.com)

October 12, 2012

Mr. Thomas Harris  
Insecticide-Rodenticide Branch  
U.S. Environmental Protection Agency  
Office of Pesticide Programs  
One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

**SUBJECT: EMAMECTIN BENZOATE**

**Pending Petition for Tolerance – Cucurbits and Application  
to add cucurbits to label for Proclaim® Insecticide (EPA  
Reg. No. 100-904)**

**Application for new product registration of ENFOLD™ for  
commercial use on ornamentals**

**EPA REQUIREMENT: INSURE EPA REPOSITORY HAS  
SPECIFIED ANALYTICAL REFERENCE STANDARDS**

Dear Mr. Harris:

The two registration actions noted in the "Subject" are pending at the EPA, and both actions have a PRIA date of October 25, 2012. With respect to these pending registrations, you informed me via e-mail that Syngenta Crop Protection LLC must insure the EPA Repository has the following:

1. An updated certificate of analysis or a new analytical reference standard for the emamectin 8,9-Z isomer of B1a (NOA 438376)
2. Analytical reference standards for MFB1a (NOA415692) and 8,9-Z B1b.

## **RESPONSE**

With the exception of the analytical reference standard for 8,9-Z B1b, Syngenta provided the requested standards/certificates of analysis to Theresa at the EPA Repository. Her accompanying e-mail of September 27, 2012 confirms that she has the analytical reference standards or updated certificates of analysis, whichever were needed, for the

emamectin 8,9-Z isomer of B1a (NOA 438376) and MFB1a (NOA415692). We were unable to provide the analytical reference standard for 8,9-Z B1b to the EPA Repository and we are requesting a waiver of this requirement. The basis for this waiver request follows.

#### **Waiver Request**

In response your recent e-mail noting the requirement to provide the analytical reference standard for 8,9-Z B1b to the EPA Repository, I forwarded the request to my Syngenta colleague who manages analytical standards and who also interacts with Theresa Cole at the EPA Repository. He said no one to his knowledge has ever produced an analytical reference standard for 8,9-Z B1b. Since Merck was the original registrant of emamectin benzoate, he decided to look into the analytical history for emamectin with respect to the tolerances and registrations for this active ingredient. In particular his goal was to determine how Merck addressed 8,9-Z B1b and how EPA responded.

This is what he found:

The original enforcement method submitted by Merck was an HPLC Fluorescence detection method. (available from EPA online). This method does not resolve the 8,9-Z isomers from the parent isomers, so B1a co-elutes with 8,9-Z B1a and it's the same for B1b. For validation, Merck fortified with an 8,9-Z B1a standard + B1a parent and by extension Merck claimed that B1b should behave similarly. So it appears Merck never produced a 8,9-Z B1b standard and because Merck did not resolve the Z isomers in their analysis EPA just set the tolerance limits based on the sums of the Z+parent components. The Novartis/Syngenta analytical method was validated with only the 8,9-Z B1a isomer as well; we've never produced the 8,9-Z B1b analytical reference standard either. In all of the storage stability studies and in everything else we have submitted to the EPA for emamectin benzoate we have only analyzed for the 8,9-Z B1a isomer. And, our current analytical method clearly indicates that we're analyzing only for the 8,9-Z B1a isomer. All of the other metabolites in the tolerance expression are listed as B1a isomers only. So it appears that only the 8,9-Z standard singles out inclusion of B1b in the tolerance expression. This is presumably based on residue studies that accompanied Merck's original tolerance petition; in those studies Merck's analytical method could not distinguish the Z isomers from parent emamectin benzoate.

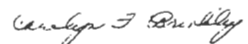
The original metabolism studies showed how little 8,9-Z B1b would be seen in a typical residue profile given the fact that the AI itself only has ~5% of B1b. In addition to Merck's analytical method for emamectin benzoate, Syngenta's EPA-approved method was validated with only the 8,9-Z B1a isomer. It appears that the EPA has historically been satisfied with the method for emamectin that only analyzes for the 8,9-Z B1a isomer which would explain why the Agency has not required an analytical reference standard for the 8,9-Z B1b isomer. Despite this history, if the Agency decided that analyzing for the 8,9-Z B1b isomer was a new requirement, it would likely take Syngenta at least a year before we could provide even a very small quantity of the 8,9-Z B1b isomer. Based on these points and the regulatory history for emamectin benzoate, Syngenta requests the EPA waive the requirement to provide an analytical reference standard for the 8,9-Z B1b

Page 2 of 2

isomer to the EPA Repository.

If you have any questions about our response and our waiver request, please call me at (336) 632 -2838.

Sincerely yours,



Carolyn F. Brinkley  
Sr. Regulatory Product Manager/ NAFTA Insecticides  
Regulatory Affairs





RE: Analytical reference standards for emamectin benzoate are needed.

carolyn.brinkley

to:

Thomas Harris

10/12/2012 02:51 PM

Hide Details

From: <carolyn.brinkley@syngenta.com>

To: Thomas Harris/DC/USEPA/US@EPA

## 2 Attachments



image001.gif Ltr to EPA emamectin - analy ref standards 10-12-12.pdf



*e-file: emamectin tolerance - (IR-4) cucurbits/ EPA requirement re: analytical ref standards at EPA Repository*

Hi Tom,

As you requested, I created a letter regarding our request for a waiver of the requirement to send an analytical reference standard for the 8,9-Z B1b isomer of emamectin to the EPA Repository. The letter includes the information and discussion in my 9-11-2012 e-mail below.

---

**From:** Thomas Harris [mailto:harris.thomas@epamail.epa.gov]

**Sent:** Tuesday, October 02, 2012 3:36 PM

**To:** Brinkley Carolyn USGR

**Subject:** Fw: Analytical reference standards for emamectin benzoate are needed.

**Importance:** High

Carolyn,

Thanks for taking care of the emamectin reference standard.

Regarding the waiver request for the metabolites, I need to do this with more official tracking and get a written memo response from HED. Please send me a letter on Syngenta letterhead with the request. Copy/paste from your note below to get the basic text and then edit a bit. Just email me a .pdf of the cover letter and I'll take care of the tracking. If we can wrap this up before the 10/25/12 due date for new cucurbits and ornamentals that would be great but not absolutely critical.

Tom Harris  
EPA/OPPTS/OPP/RD/IRB  
voice: (703) 308-9423  
fax: (703) 308-0029  
[harris.thomas@epa.gov](mailto:harris.thomas@epa.gov)  
visit <http://www.epa.gov/pesticides>

----- Forwarded by Thomas Harris/DC/USEPA/US on 10/02/2012 03:28 PM -----

From: Nancy Dodd/DC/USEPA/US  
To: Thomas Harris/DC/USEPA/US@EPA  
Cc: Steve Funk/DC/USEPA/US@EPA, Leung Cheng/DC/USEPA/US@EPA, Meheret Negussie/DC/USEPA/US@EPA, Amelia Acierto/DC/USEPA/US@EPA  
Date: 10/02/2012 02:32 PM  
Subject: Re: Fw: Analytical reference standards for emamectin benzoate are needed.

---

I think an official paper request tracked in OPPIN would be a good way to document the issue for future reference.

Thomas Harris---10/02/2012 12:49:33 PM---Nancy, Cleaning my emails from when I was on vacation. This one is asking for a waiver to supply an

From: Thomas Harris/DC/USEPA/US  
To: Nancy Dodd/DC/USEPA/US@EPA  
Cc: Jeff Dawson/DC/USEPA/US@EPA  
Date: 10/02/2012 12:49 PM  
Subject: Fw: Analytical reference standards for emamectin benzoate are needed.

---

Nancy,

Cleaning my emails from when I was on vacation. This one is asking for a waiver to supply an analytical reference standard for a metabolite that you had asked for.

>>> Question: what is the proper way to request this waiver? I think we probably need an official paper request tracked in OPPIN (I might be able to create it from this email) with a DP to HED for an official memo response. What do you think?

Tom Harris  
EPA/OPPTS/OPP/RD/IRB  
voice: (703) 308-9423  
fax: (703) 308-0029  
[harris.thomas@epa.gov](mailto:harris.thomas@epa.gov)  
visit <http://www.epa.gov/pesticides>

----- Forwarded by Thomas Harris/DC/USEPA/US on 10/02/2012 12:46 PM -----

From: <[carolyn.brinkley@syngenta.com](mailto:carolyn.brinkley@syngenta.com)>  
To: Thomas Harris/DC/USEPA/US@EPA  
Date: 09/11/2012 04:13 PM  
Subject: RE: FW: Analytical reference standards for emamectin benzoate are needed.

*E-FILE: emamectin petition for tolerance cucurbits - EPA requirement to submit analytical reference standards*

Hi Tom,

Responding to your message regarding the pending IR-4 petition for an emamectin tolerance in/on cucurbits and analytical standards for emamectin.

Nancy Dodd said, in her e-mail to Barbara Madden below, that we need to send the following to Theresa Cole at the EPA Repository Analytical Chemistry Lab in Fort Meade.:

1. An updated certificate of analysis or a new analytical reference standard for the emamectin 8,9-Z isomer of B1a (NOA 438376)
2. Analytical reference standards for MFB1a (NOA415692) and 8,9-Z B1b.

RESPONSE

1. DONE: We sent an updated certificate of analysis for the emamectin isomer standard to Theresa Cole. (I'll look for written documentation - may just be an e-mail)
2. WAIVER REQUEST: We can't provide the requested standards for MFB1a (NOA415692) and 8,9-Z B1b and are requesting a waiver of this requirement for several reasons. Details follow.

I forwarded the request for these analytical standards to my Syngenta colleague who manages analytical standards.

- He said no one to his knowledge has ever produced analytical reference standards for these metabolites.
- Since Merck was the original registrant of emamectin, he decided to look into the analytical history for emamectin with respect to the tolerances and registrations EPA approved for emamectin when Merck was the registrant.
  - Here's what he found and the basis for our request to waive the requirement to provide these particular analytical reference standards to the Repository

The original enforcement method submitted by Merck was an HPLC Fluorescence detection method which is available from EPA online. This method does not resolve the 8,9Z isomers from the parent isomers, so B1a coelutes with 8,9Z B1a and it's the same for B1b. For validation, Merck fortified with an 8,9Z B1a standard + B1a parent and by extension Merck claimed that B1b should behave similarly. So it appears Merck never produced a 8,9Z B1b standard and because Merck did not resolve the Z isomers in their analysis EPA just set the tolerance limits based on the sums of the Z+parent components.



The Novartis/Syngenta analytical method was validated with only the 8,9Z B1a isomer as well; we've never produced the 8,9Z B1b standard either. In all of the storage stability studies and in everything else we have submitted to the EPA for emamectin we have only analyzed for the 8,9Z B1a isomer. And our current method clearly indicates that we're analyzing only for 8,9Z B1a. All of the other metabolites in the tolerance expression are listed as B1a isomers only. So it appears that only the 8,9Z standard singles out inclusion of B1b in the tolerance expression. This is presumably due to the original petition from Merck in which they could not distinguish the Z isomers from parent in their analytical method. We believe the original metabolism shows how little 8,9Z B1b would be seen in a typical residue profile given that the AI itself only has ~5% of B1b.

PLEASE LET ME KNOW IF OUR WAIVER REQUEST IS ACCEPTABLE

**From:** Thomas Harris [<mailto:harris.thomas@epamail.epa.gov>]  
**Sent:** Thursday, August 02, 2012 12:24 PM  
**To:** Brinkley Carolyn USGR  
**Cc:** Parshley Tom USGR  
**Subject:** Fw: Analytical reference standards for emamectin benzoate are needed.

Carolyn,

Can you take care of this before October? I don't want to have to deal with it in an acceptance letter; much easier to resolve beforehand. I'm assuming this is fairly simply but feel free to correct me!

Assuming you can easily resolve this, please cc me on the correspondence sent to the Fort Meade lab (a copy sent by email would be great) so I can show it's resolved before we get to stamping the label.

Tom Harris  
 EPA/OPPTS/OPP/RD/IRB  
 voice: (703) 308-9423  
 fax: (703) 308-0029  
[harris.thomas@epa.gov](mailto:harris.thomas@epa.gov)  
 visit <http://www.epa.gov/pesticides>

----- Forwarded by Thomas Harris/DC/USEPA/US on 08/02/2012 12:19 PM -----

From: Barbara Madden/DC/USEPA/US  
 To: Thomas Harris/DC/USEPA/US@EPA  
 Cc: John Hebert/DC/USEPA/US@EPA, Andrew Ertman/DC/USEPA/US@EPA  
 Date: 08/02/2012 11:55 AM  
 Subject: Fw: Analytical reference standards for emamectin benzoate are needed.

Tom,

I imagine this could be a condition of registration? Or is this no longer allowed to be a condition? Something

you may want to share with the registrant because if this cannot be a condition we are not going to make an October date unless they satisfy this. Let me know. Thanks Barbara

— Forwarded by Barbara Madden/DC/USEPA/US on 08/02/2012 11:52 AM —

From: Nancy Dodd/DC/USEPA/US

To: Barbara Madden/DC/USEPA/US@EPA, Andrew Ertman/DC/USEPA/US@EPA

Date: 08/02/2012 10:54 AM

Subject: Analytical reference standards for emamectin benzoate are needed.

---

IR-4 has a petition on cucurbits. Analytical reference standards need to be sent to the repository as stated below.

- **The standard for emamectin 8,9-Z isomer of B1a (NOA 438376) expired on 3/31/2012. An updated certificate of analysis or a new analytical reference standard must be provided to the EPA National Pesticide Standards Repository.**
- **Analytical reference standards for MFB1a (NOA415692) and 8,9-Z B1b are currently unavailable at the Repository. Analytical reference standards must be provided.**

The new standards should be sent to the Analytical Chemistry Lab, which is located at Fort Meade, to the attention of Theresa Cole at the following address:

USEPA  
National Pesticide Standards Repository/Analytical Chemistry Branch/OPP  
701 Mapes Road  
Fort George G. Meade, MD 20755-5350

(Note that the mail will be returned if the extended zip code is not used.)

Nancy Dodd

---

*This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.*

---

*This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.*

---

*This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.*





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND  
POLLUTION PREVENTION**MEMORANDUM****Date:** 1/9/13**SUBJECT:** Emamectin Benzoate. Revised Human Health Risk Assessment for Proposed Uses on Cucurbits and Outdoor-Grown Plants in Commercial Nursery Production.**PC Code:** 122806**Decision No.:** 452138**Petition No.:** NA**Risk Assessment Type:** Single Chemical/Aggregate**TXR No.:** NA**MRID No.:** NA**DP Barcode:** D393837**Registration No.:** 100-904, 100-RURR**Regulatory Action:** Section 3 Registration**Case No.:** NA**CAS No.:** 155569-91-8**40 CFR:** 180.505

**FROM:** Nancy Dodd, Chemist and Risk Assessor  
Nancy Tsaur, Chemist  
Whang Phang, Toxicologist  
Risk Assessment Branch III (RAB3)  
Health Effects Division (HED; 7509P)

**THROUGH:** Jeff Dawson, Acting Branch Chief  
RAB3/HED (7509P)

**TO:** Barbara Madden/Andrew Ertman, RM#5  
Risk Integration, Minor Use, and Emergency Response Branch  
Registration Division (RD; 7505P)

The Health Effects Division (HED) of the Office of Pesticide Programs (OPP) is charged with estimating the risk to human health from exposure to pesticides. The Registration Division (RD) of OPP has requested that HED evaluate hazard and exposure data and conduct dietary, occupational, residential, and aggregate exposure assessments, as needed, to estimate the risk to human health that will result from the proposed uses of emamectin benzoate (a benzoate salt mixture of a minimum of 90% 4'-epi-methylamino-4'-deoxyavermectin B<sub>1a</sub> and a maximum of 10% 4'-epi-methylamino-4'-deoxyavermectin B<sub>1b</sub>) and its isomers/metabolites/degradates. The Interregional Research Project No. 4 (IR-4) has proposed to register the use and establish a tolerance on cucurbit vegetables (Crop Group 9). Syngenta has also proposed to register use on outdoor-grown ornamental plants in commercial nursery production, including field- and container-grown ornamentals. This revised memo incorporates results using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-

FCID), Version 3.16.

A summary of the findings and an assessment of human risk resulting from the registered and proposed uses for emamectin benzoate are provided in this document. The residue chemistry review, dietary assessment, and overall risk assessment were performed by Nancy Dodd. The occupational/residential assessment was performed by Nancy Tsaor. The toxicology assessment was performed by Whang Phang. The drinking water exposure assessment was performed by Tiffany Downen of the Environmental Fate & Effects Division (EFED).



## TABLE OF CONTENTS

|       |                                                                                |    |
|-------|--------------------------------------------------------------------------------|----|
| 1.0   | Executive Summary .....                                                        | 5  |
| 2.0   | HED Recommendations .....                                                      | 8  |
| 2.1   | Data Deficiencies .....                                                        | 8  |
| 2.2   | Tolerance Considerations .....                                                 | 10 |
| 2.2.1 | Enforcement Analytical Method .....                                            | 10 |
| 2.2.2 | International Harmonization .....                                              | 10 |
| 2.2.3 | Recommended Tolerances .....                                                   | 10 |
| 2.2.4 | Revisions to Petitioned-For Tolerances .....                                   | 11 |
| 2.3   | Label Recommendations .....                                                    | 11 |
| 2.3.1 | Recommendations from Residue Reviews .....                                     | 11 |
| 2.3.2 | Recommendations from Occupational Assessment .....                             | 11 |
| 2.3.3 | Recommendations from Residential Assessment .....                              | 13 |
| 3.0   | Introduction .....                                                             | 13 |
| 3.1   | Chemical Identity .....                                                        | 13 |
| 3.2   | Physical/Chemical Characteristics .....                                        | 14 |
| 3.3   | Pesticide Use Patterns .....                                                   | 15 |
| 3.4   | Anticipated Exposure Pathways .....                                            | 17 |
| 3.5   | Consideration of Environmental Justice .....                                   | 17 |
| 4.0   | Hazard Characterization and Dose-Response Assessment .....                     | 18 |
| 4.1   | Summary of Toxicological Effects .....                                         | 18 |
| 4.2   | Safety factor for Infants and Children (FQPA Safety Factor) .....              | 21 |
| 4.2.1 | Completeness of the Toxicology Database .....                                  | 21 |
| 4.2.2 | Evidence of Neurotoxicity .....                                                | 22 |
| 4.2.3 | Evidence of Sensitivity/Susceptibility in the Developing or Young Animal ..... | 22 |
| 4.2.4 | Residual Uncertainty in the Exposure Database .....                            | 22 |
| 4.3   | Toxicity Endpoint and Point of Departure Selections .....                      | 23 |
| 5.0   | Dietary Exposure and Risk Assessment .....                                     | 25 |
| 5.1   | Residues of Concern Summary and Rationale .....                                | 25 |
| 5.2   | Food Residue Profile .....                                                     | 27 |
| 5.3   | Water Residue Profile .....                                                    | 28 |
| 5.4   | Dietary Risk Assessment .....                                                  | 29 |
| 5.4.1 | Description of Residue Data Used in Dietary Assessment .....                   | 29 |
| 5.4.2 | Percent Crop Treated Used in Dietary Assessment .....                          | 30 |
| 5.4.3 | Acute Dietary Risk Assessment .....                                            | 30 |
| 5.4.4 | Chronic Dietary Risk Assessment .....                                          | 31 |
| 5.4.5 | Cancer Dietary Risk Assessment .....                                           | 31 |
| 5.4.6 | Summary Tables .....                                                           | 31 |
| 6.0   | Residential (Non-Occupational) Exposure/Risk Characterization .....            | 33 |
| 6.1   | Residential Handler Exposure .....                                             | 33 |
| 6.2   | Post-Application Exposure .....                                                | 33 |
| 6.3   | Residential Bystander Post-application Inhalation Exposure .....               | 33 |
| 6.4   | Spray Drift .....                                                              | 34 |

|                                                                     |                                                          |           |
|---------------------------------------------------------------------|----------------------------------------------------------|-----------|
| <b>7.0</b>                                                          | <b>Aggregate Exposure/Risk Characterization .....</b>    | <b>34</b> |
| 7.1                                                                 | Acute Aggregate Risk.....                                | 34        |
| 7.2                                                                 | Short-/Intermediate-Term Aggregate Risk .....            | 34        |
| 7.3                                                                 | Chronic Aggregate Risk .....                             | 35        |
| 7.4                                                                 | Cancer Aggregate Risk .....                              | 35        |
| <b>8.0</b>                                                          | <b>Cumulative Exposure/Risk Characterization .....</b>   | <b>35</b> |
| <b>9.0</b>                                                          | <b>Occupational Exposure/Risk Characterization .....</b> | <b>36</b> |
| 9.1                                                                 | Short-/Intermediate-Term Handler Risk.....               | 36        |
| 9.2                                                                 | Short-/Intermediate-Term Post-Application Risk .....     | 39        |
| 9.2.1                                                               | Dermal Post-Application Risk.....                        | 39        |
| 9.2.2                                                               | Occupational Post-Application Inhalation Exposure .....  | 39        |
| <b>10.0</b>                                                         | <b>References .....</b>                                  | <b>40</b> |
| <b>Appendix A. Toxicology Profile and Executive Summaries .....</b> |                                                          | <b>42</b> |
| A.1                                                                 | Toxicology Data Requirements .....                       | 42        |
| A.2                                                                 | Toxicity Profiles.....                                   | 43        |
| <b>Appendix B. Physical/Chemical Properties .....</b>               |                                                          | <b>51</b> |
| <b>Appendix C. Review of Human Research.....</b>                    |                                                          | <b>52</b> |
| <b>Appendix D. Occupational Exposure/Risk Summary Tables.....</b>   |                                                          | <b>53</b> |
| <b>Appendix E. International Tolerances.....</b>                    |                                                          | <b>60</b> |
| <b>Appendix F. Toxicology Literature References .....</b>           |                                                          | <b>61</b> |



## 1.0 Executive Summary

**Use Profile:** Emamectin benzoate will be applied as a 5% soluble granule (SG) formulation (Proclaim® Insecticide; EPA Reg. No. 100-904) to cucurbits for control of armyworms, cabbage looper, corn earworm, melon worm, rindworms, tobacco budworm, pickleworm, and *Lirioyza* leaf miners. Proclaim® Insecticide may be applied as a foliar spray via aircraft (except in New York State) or groundboom. Chemigation is prohibited. For high pest infestations, the maximum single application rate is 4.8 oz/A (0.015 lb ai/A). Applications may be repeated at a 7-day interval to maintain control, up to a maximum seasonal application rate of 28.8 oz/A (0.090 lb ai/A/season). The preharvest interval (PHI) is 6 days. The proposed restricted entry interval (REI) is 12 hours.

Emamectin benzoate is also proposed for use on outdoor-grown plants in commercial nursery production to control lepidopterous larvae (worms/caterpillars) and to suppress leaf miners and spider mites. Enfold™ Insecticide (EPA Reg. No. 100-RURR), a 5% SG formulation, may be applied as a foliar spray via groundboom, airblast, or aircraft (except in New York State). Chemigation is prohibited. For high pest infestations, the maximum single application rate is 4.8 oz/A (0.015 lb ai/A). Applications may be repeated at a 7- to 14- day interval to maintain control, up to a maximum seasonal application rate of 28.8 oz/A (0.090 lb ai/A/season). The proposed REI is 12 hours.

### Human Health Risk Assessment:

**Toxicity/Hazard:** Emamectin has moderate acute toxicity by the oral route and low acute toxicity by the dermal route. It is not irritating to the skin, nor is it a dermal sensitizer, but it is a severe eye irritant. The main target tissue is the nervous system, with neuropathology detected in many studies and several species. The dose-response curve was very steep in several studies (most notably with CF-1 mice and dogs), with severe effects (morbid sacrifice and neuropathology) sometimes seen at the lowest observable adverse effect levels (LOAELs). Although no increased sensitivity was seen in developmental toxicity studies in rats and rabbits, increased qualitative and/or quantitative sensitivity of rat pups was seen in the reproductive toxicity study and in the developmental neurotoxicity study. Review of acceptable oncogenicity and mutagenicity studies provide no indication that emamectin is carcinogenic or mutagenic. Emamectin is classified as "not likely to be carcinogenic to humans."

**Dietary Exposure (food/drinking water):** Acute and chronic dietary (food and drinking water) exposure and risk assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID), Version 3.16. The acute dietary exposure assessment was a probabilistic assessment for food and drinking water using anticipated residues based on field trial data. The chronic dietary exposure assessment was a somewhat refined assessment for food and drinking water using single point estimates (averages) of anticipated residues based on field trials. Refinements for both the acute and chronic assessments included using percent crop treated for some new and registered crops, DEEM



default processing factors where appropriate, chemical-specific processing factors where available, and anticipated residues based on field trial data for most crops. For the acute assessment, Pesticide Monitoring Program (PDP) monitoring data were used for apples since apple juice contributed significantly to the exposure. The 10X FQPA safety factor was retained for chronic assessments and reduced to 3X for acute assessments.

The estimated drinking water concentrations (EDWCs) of emamectin benzoate were provided by EFED. A drinking water residue distribution based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) modeling of the use on ornamentals was used in the acute assessment. An EDWC based on the PRZM/EXAMS modeling of the use on ornamentals was used for the chronic assessment.

The acute dietary exposure estimates for food and drinking water using the ornamentals scenario for drinking water are below HED's level of concern at the 99.9<sup>th</sup> percentile of exposure for all population subgroups (36% of the acute population adjusted dose [aPAD] for the general U.S. population and 60% of the aPAD for children 1-2 years old, the population with the highest exposure).

The chronic dietary exposure estimates for food and drinking water using the ornamentals scenario for drinking water are below HED's level of concern for all population subgroups (7.5% of the chronic population adjusted dose [cPAD] for the general U.S. population and 16% of the cPAD for all infants less than 1 year old, the population with the highest exposure).

**Residential Exposure:** There are no existing or proposed residential use sites; therefore, residential handler exposure and residential post-application exposure are not expected. Emamectin benzoate is registered for agricultural uses, as a tree injection use, and as a cockroach bait. Except for Optigard<sup>TM</sup> Cockroach Bait (EPA Reg. No. 100-1290), all registered emamectin benzoate end-use products are restricted use products (RUPs; restricted to use by professional certified operators [PCOs] only). Optigard<sup>TM</sup> Cockroach Bait is not a restricted use product but EPA has indicated that it is to be used only in commercial and industrial areas. Proclaim<sup>®</sup> Insecticide is an RUP which is proposed for use on cucurbits. Enfold<sup>TM</sup> Insecticide is an RUP which is proposed for use on outdoor-grown plants in commercial nursery production. Residential exposures from commercial nursery production are expected to be negligible because the emamectin is expected to dissipate by the time the plant moves from a nursery, through a retail store, to the consumer.

**Aggregate Risk:** The acute aggregate risk assessment takes into account exposure estimates from dietary (food and drinking water) consumption of emamectin as discussed above.

Short- and intermediate-term aggregate risk assessments were not conducted because residential exposure is not expected from existing or proposed uses.

The long-term aggregate risk assessment takes into account average exposure estimates from



dietary consumption of emamectin benzoate (food and drinking water) and residential uses. However, residential exposures are not expected; therefore, the chronic aggregate risk assessment will consider only exposure from food and drinking water, which is discussed above.

**Occupational Exposure/Risk:**Occupational Handlers

There is potential for short- and intermediate-term occupational exposure to emamectin benzoate during handling activities (e.g. mixing, loading, application) for the proposed uses (cucurbit vegetables and outdoor-grown ornamentals). However, intermediate-term exposure is less likely due to resistance management, and short-term scenarios are more realistic. Emamectin is a Group 6 insecticide that has inherent risks of resistance development. It is strongly advised to be used in a sound resistance management program. Due to changes in unit exposure values and body weight assumptions, all of the occupational handler exposure and risk estimate tables have been updated in this document since the two occupational and residential exposure (ORE) risk assessments previously conducted by Nancy Tsaur (DP390778, 12/07/2011; and DP393839, 03/01/2012).

Based on the personal protective equipment (PPE) required on the labels, there are some risks of concern. Table 9.1 shows the PPE proposed on both labels (EPA Reg. No. 100-904 and EPA Reg. No. 100-RURR) along with mitigation recommendations based on short- and intermediate-term risk estimates. In order to achieve risk estimates that do not exceed HED's level of concern (LOC; Aggregate Risk Indexes [ARIs] > 1.0), the recommendations based on intermediate-term exposure are more stringent. However, when considering resistance management, the short-term risk estimates are more representative of realistic exposure potential.

Occupational Post-Application

There is a potential for short- and intermediate-term occupational exposure during post-application activities. However, intermediate-term exposure is less likely due to resistance management, and short-term scenarios are more realistic. HED recommends utilizing the results from the short-term quantitative risk assessment because the intermediate-term results are highly conservative and unlikely. For short-term exposure duration, all scenarios resulted in margins of exposure (MOEs) greater than the short-term LOC of 300 (ranging from 520 to 11,000) on day 0 (12 hours after application) and, therefore, are not of concern to HED.

Restricted Entry Interval

Typically, under the Worker Protection Standard (WPS) for Agricultural Pesticides, active ingredients classified as acute Toxicity Category III or IV for acute dermal, eye irritation, and primary skin irritation are assigned a 12-hour REI.

**Environmental Justice Considerations:**

Environmental justice concerns were considered in this assessment. Refer to Section 3.5.



**Review of Human Research:**

This risk assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide or other chemical. These studies (listed in Appendix C) have been determined to require a review of their ethical conduct, and have received that review.

**Additional Data Needs:**

Provided a revised Section F and some analytical reference standards are submitted before registration, the dietary-exposure database will be adequate to support the proposed registration on cucurbits. There is sufficient information available to assess occupational handler exposure to emamectin benzoate. The toxicology database for emamectin benzoate is largely complete. However, an immunotoxicity study (OPPTS Guideline Number 870.7800) is now required for conventional pesticide registration (40 CFR Part 158). Additionally, a subchronic (28-day) inhalation toxicity study (OPPTS GLN 870.3465) is needed for a more accurate assessment of toxicity via the inhalation route, and for inhalation risk assessments for exposures associated with the existing and proposed use patterns.

**2.0 HED Recommendations**

Provided a revised Section F and analytical reference standards are submitted, HED can recommend for a registration and tolerance for the use of emamectin benzoate on cucurbit vegetables and for registration of the use on outdoor-grown ornamental plants in commercial nursery production. Additional data are needed as outlined in Section 2.1 below. The specific tolerance recommendations are discussed in Section 2.2, and label modifications are discussed in Section 2.3.

**2.1 Data Deficiencies**

**Data that needs to be submitted prior to establishing a tolerance or allowing a registration:**

*Residue Chemistry*OPPTS 860.1550 Proposed Tolerance

- A revised Section F must be submitted proposing a tolerance for Vegetable, cucurbit, group 9 at 0.02 ppm.

OPPTS 860.1650 Submittal of Analytical Reference Standards

- The standard for the 8,9-Z isomer of B<sub>1a</sub> (NOA 438376) expired on 3/31/2012. An updated certificate of analysis or a new analytical reference standard must be provided to the EPA National Pesticide Standards Repository. — *done August 2012 9/27/12*
- Analytical reference standards for MFB<sub>1a</sub> (NOA415692) and 8,9-Z B<sub>1b</sub> are currently unavailable at the Repository. Analytical reference standards must be provided.

Toxicology

*waiver submitted 10/12/12 100-904  
granted 11/20/12*

870.3465 Subchronic Inhalation

- A subchronic inhalation study is needed. HED determined there was a data gap for a 28-day inhalation study. This study should be performed using the CF-1 mouse.

*— preliminary 28-day inhalation submitted 11/7/11  
— need for 28-day inhalation & use of CF-1 mouse deferred until req review  
see HED 11/15/11 memo NDodd to M Manibwong*

870.7800 Immunotoxicity

- An immunotoxicity study is needed. *submitted 10/24/12 to RD; turned over to PRD for req review*

Occupational Exposure

*Dislodgeable Foliar Residue (DFR):* In accordance with the updated Part 158 data requirements (2007), one or more DFR studies are required when a pesticide has residential or occupational uses that could result in post-application dermal exposure. As part of the recent revision to the *Health Effects Division's 2012 Standard Operating Procedures for Residential Pesticide Exposure Assessment*, HED analyzed a number of DFR studies and selected a new default value for the fraction of the application rate available to be dislodged after a foliar application (F<sub>AR</sub>). This default value is 25% and is based on an analysis of 19 DFR studies where the F<sub>AR</sub> value ranged from 2% to 89%. This value is recommended for use in both residential and occupational postapplication assessments. Of the analyzed DFR studies, the maximum F<sub>AR</sub> value seen was 89% or 3.6 times higher than the default residue transfer value. Therefore, the HED has decided that a calculated MOE of approximately 4 times higher than the level of concern (e.g., an MOE > 400 if the LOC = 100) using the default dislodged residue values would provide an adequate margin of safety for any potentially higher residues seen in a chemical-specific DFR study (*Guidance for Requiring/Waiving Turf Transferrable Residue (TTR) and Dislodgeable Foliar Residue (DFR) Studies*, 6/7/2012, Exposure Science Advisory Council). A DFR study is required for emamectin benzoate at this time since the dermal MOE is less than 4 times the LOC based on default values for the fraction of application rate available for transfer after a foliar application.



## 2.2 Tolerance Considerations

### 2.2.1 Enforcement Analytical Method

Adequate methods (Method 244-92-3 and Method 244-92-3, Revision 1) are available for the enforcement of tolerances on plants. The methods determine residues of emamectin (the free base) and its regulated isomers and degradates/metabolites using high performance liquid chromatography with fluorescence detection (HPLC/FLD). The methods determine residues of emamectin in the following analyte combinations:  $MAB_{1a} + 8,9-ZB_{1a}$ ,  $MAB_{1b} + 8,9-ZB_{1b}$ ,  $AB_{1a}$ , and  $MFB_{1a} + FAB_{1a}$ , with a limit of quantitation (LOQ) of 0.005 ppm for each analyte or analyte combination, for a combined LOQ of 0.02 ppm.

### 2.2.2 International Harmonization

Codex (Report of the Codex Alimentarius Commission, Rome, 2012) has a proposed tolerance on cucurbits at 0.007 ppm for residues of emamectin B<sub>1a</sub> benzoate, expressed as emamectin (free base). EPA is recommending a tolerance of 0.02 ppm for the use of emamectin benzoate on cucurbits; the tolerance is to be expressed as the combined residues of emamectin (free base) as described in section 2.2.3 below. There are no established or proposed Canadian or Mexican MRLs for residues of emamectin benzoate on cucurbits (Appendix E).

### 2.2.3 Recommended Tolerances

The proposed and recommended tolerances for cucurbit vegetables are presented in Table 2.2.3.

The tolerance expression proposed by the petitioner is appropriate, but should be revised by RD according to HED's Interim Guidance on Tolerance Expressions (5/27/09, S. Knizner) as follows:

Under 40 CFR §180.505(a)(1) for plant commodities: "Tolerances are established for emamectin, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of emamectin (a mixture of a minimum of 90% 4'-epi-methylamino-4'-deoxyavermectin B<sub>1a</sub> and maximum of 10% 4'-epi-methylamino-4'-deoxyavermectin B<sub>1b</sub>) and its metabolites 8,9-isomer of the B<sub>1a</sub> and B<sub>1b</sub> component of the parent (8,9-ZMA), or 4'-deoxy-4'-epi-amino-avermectin B<sub>1a</sub> and 4'-deoxy-4'-epi-amino-avermectin B<sub>1b</sub>; 4'-deoxy-4'-epi-amino avermectin B<sub>1a</sub> (AB<sub>1a</sub>); 4'-deoxy-4'-epi-(N-formyl-N-methyl)amino-avermectin (MFB<sub>1a</sub>); and 4'-deoxy-4'-epi-(N-formyl)amino-avermectin B<sub>1a</sub> (FAB<sub>1a</sub>), calculated as the stoichiometric equivalent of emamectin."

Under 40 CFR §180.505(a)(2) for livestock commodities: "Tolerances are established for emamectin, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by



measuring only the sum of emamectin ( $MAB_{1a} + MAB_{1b}$  isomers) and the associated 8,9-Z isomers ( $8,9-ZB_{1a}$  and  $8,9-ZB_{1b}$ )."

**Table 2.2.3. Tolerance Summary for Emamectin**

| Commodity                    | Proposed Tolerance (ppm) | Recommended Tolerance (ppm) | Comments<br><i>Correct Commodity Definition</i> |
|------------------------------|--------------------------|-----------------------------|-------------------------------------------------|
| Vegetable, cucurbit, group 9 | 0.03                     | 0.02                        |                                                 |

#### 2.2.4 Revisions to Petitioned-For Tolerances

HED attributes the difference between the recommended tolerance and the proposed tolerance (as shown in Table 2.2.3) to the difference in the way the petitioner reported combined residues in the cucumber submissions. The petitioner reported the combined LOQ in the cucumber study as 0.025 ppm, reflecting the sum of  $MAB_{1a}/8,9-ZB_{1a} + MAB_{1b}/8,9-ZB_{1b} + AB_{1a} + MFB_{1a} + FAB_{1a}$ ; however, the analytical method determines residues of  $MFB_{1a}$  and  $FAB_{1a}$  as a single component; therefore, the combined LOQ should have been 0.02 ppm.

### 2.3 Label Recommendations

#### 2.3.1 Recommendations from Residue Reviews

None.

#### 2.3.2 Recommendations from Occupational Assessment

*Dislodgeable Foliar Residue (DFR)*: In accordance with the updated Part 158 data requirements (2007), one or more DFR studies are required when a pesticide has residential or occupational uses that could result in post-application dermal exposure. As part of the recent revision to the *Health Effects Division's 2012 Standard Operating Procedures for Residential Pesticide Exposure Assessment*, HED analyzed a number of DFR studies and selected a new default value for the fraction of the application rate available to be dislodged after a foliar application ( $F_{AR}$ ). This default value is 25% and is based on an analysis of 19 DFR studies where the  $F_{AR}$  value ranged from 2% to 89%. This value is recommended for use in both residential and occupational postapplication assessments. Of the analyzed DFR studies, the maximum  $F_{AR}$  value seen was 89% or 3.6 times higher than the default residue transfer value. Therefore, the HED has decided that a calculated MOE of approximately 4 times higher than the level of concern (e.g., an MOE > 400 if the LOC = 100) using the default dislodged residue values would provide an adequate margin of safety for any potentially higher residues seen in a chemical-specific DFR study (*Guidance for Requiring/Waiving Turf Transferrable Residue (TTR) and Dislodgeable Foliar Residue (DFR) Studies*, 6/7/2012, Exposure Science Advisory Council). A DFR study is required for emamectin benzoate at this time since the dermal MOE is less than 4 times the LOC based on default values for the fraction of application rate available for transfer after a foliar application.



Occupational Handlers – Cucurbits (Proclaim® Insecticide)

There is potential for short- and intermediate-term occupational exposure to emamectin benzoate during handling activities (e.g. mixing, loading, application).

All the values in the tables have been updated since the ORE review (N. Tsaur, DP Number D393839, 03/01/2012) to reflect policy changes (i.e., inhalation toxicity uncertainty factors).

Based on the PPE required on the label (see Table 9.1), there are risks of concern. To achieve MOEs that do not exceed HED's LOC (ARIs > 1.0), the following mitigation should be required in addition to the current label requirements for the following scenarios:

For short-term exposure, mixing/loading dry flowables for groundboom application requires double layer clothing + gloves and PF10 respirators. Mixing/loading dry flowables for aerial application requires engineering controls of water soluble packaging.

For intermediate-term exposure, mixing/loading dry flowables for groundboom application and flagging for aerial application require double layer clothing + gloves and PF10 respirators. Mixing/loading dry flowables for aerial application requires engineering controls of water soluble packaging.

Occupational Handlers – Ornamentals (Enfold™ Insecticide)

There is potential for short- and intermediate-term occupational exposure to emamectin benzoate during handling activities (e.g. mixing, loading, application).

All the values in the tables have been updated since the ORE review (N. Tsaur, DP Number D390788, 12/07/2011) to reflect policy changes (i.e., body weight assumptions and inhalation toxicity uncertainty factors).

Based on the PPE required on the label (see Table 9.1), there are risks of concern. To achieve MOEs that do not exceed HED's LOC (ARIs > 1.0), the following mitigation should be required:

For short-term exposure, mixing/loading dry flowables for groundboom and airblast application require double layer clothing + gloves and PF10 respirators. Mixing/loading dry flowables for aerial application requires engineering controls of water soluble packaging. Open cab airblast is acceptable with PF10 respirators. Handheld equipment is acceptable if gloves are required.

For intermediate-term exposure, mixing/loading dry flowables for groundboom and airblast application require double layer clothing + gloves and PF10 respirators. Mixing/loading dry flowables for aerial application requires engineering controls of water

soluble packaging. The high exposures expected from open cab airblast applications are best mitigated by requiring an enclosed cab system. Handheld equipment is not of concern if PF5 respirators are required.

#### Label Recommendation (Enfold™ Insecticide)

The label must indicate the required PPE for handheld applications as listed in Table 9.1 (i.e., applications via backpack sprayers or manually pressurized handwands).

### **2.3.3 Recommendations from Residential Assessment**

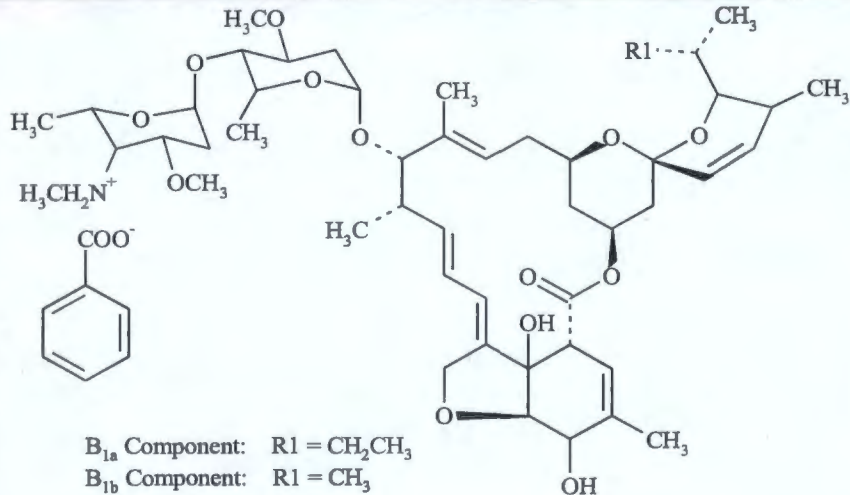
Residential exposure is not expected from the registered/proposed products since they are agricultural uses rather than residential uses, restricted use products (restricted to use by certified applicators only), or limited to non-residential areas (commercial and industrial areas). There are no proposed/registered products that would lead to residential handler or post-application exposure. Residential exposures from commercial nursery production are expected to be negligible because the emamectin is expected to dissipate by the time the plant moves from a nursery, through a retail store, to the consumer.

## **3.0 Introduction**

### **3.1 Chemical Identity**

Emamectin benzoate is a semi-synthetic avermectin, consisting of two active homologous compounds (a benzoate salt mixture of a minimum of 90% 4'-epi-methylamino-4'-deoxyavermectin B<sub>1a</sub> and a maximum of 10% 4'-epi-methylamino-4'-deoxyavermectin B<sub>1b</sub>).



| Table 3.1 Test Compound Nomenclature |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|--------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Chemical Structure                   |  <p> <math>B_{1a}</math> Component: <math>R1 = CH_2CH_3</math><br/> <math>B_{1b}</math> Component: <math>R1 = CH_3</math> </p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Empirical Formula                    | emamectin benzoate $B_{1a}$ : $C_{49}H_{75}NO_{13} \cdot C_7H_6O_2$<br>emamectin benzoate $B_{1b}$ : $C_{48}H_{73}NO_{13} \cdot C_7H_6O_2$                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Common Name                          | emamectin benzoate                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Company experimental name            | MK244                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| IUPAC name                           | Mixture of (10 <i>E</i> ,14 <i>E</i> ,16 <i>E</i> )-(1 <i>R</i> ,4 <i>S</i> ,5' <i>S</i> ,6 <i>S</i> ,6' <i>R</i> ,8 <i>R</i> ,12 <i>S</i> ,13 <i>S</i> ,20 <i>R</i> ,21 <i>R</i> ,24 <i>S</i> )-6'-[( <i>S</i> )- <i>sec</i> -butyl]-21,24-dihydroxy-5',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.1 <sup>4,8</sup> .0 <sup>20,24</sup> ]]pentacosa-10,14,16,22-tetraene)-6-spiro-2'-(5',6'-dihydro-2' <i>H</i> -pyran)-12-yl 2,6-dideoxy-3- <i>O</i> -methyl-4- <i>O</i> -(2,4,6-trideoxy-3- <i>O</i> -methyl-4-methylamino- $\alpha$ - <i>L</i> - <i>lyxo</i> -hexapyranosyl)- $\alpha$ - <i>L</i> - <i>arabino</i> -hexapyranoside benzoate and (10 <i>E</i> ,14 <i>E</i> ,16 <i>E</i> )-(1 <i>R</i> ,4 <i>S</i> ,5' <i>S</i> ,6 <i>S</i> ,6' <i>R</i> ,8 <i>R</i> ,12 <i>S</i> ,13 <i>S</i> ,20 <i>R</i> ,21 <i>R</i> ,24 <i>S</i> )-21,24-dihydroxy-6'-isopropyl-5',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo[15.6.1.1 <sup>4,8</sup> .0 <sup>20,24</sup> ]]pentacosa-10,14,16,22-tetraene)-6-spiro-2'-(5',6'-dihydro-2' <i>H</i> -pyran)-12-yl 2,6-dideoxy-3- <i>O</i> -methyl-4- <i>O</i> -(2,4,6-trideoxy-3- <i>O</i> -methyl-4-methylamino- $\alpha$ - <i>L</i> - <i>lyxo</i> -hexapyranosyl)- $\alpha$ - <i>L</i> - <i>arabino</i> -hexapyranoside benzoate |
| CAS Name                             | (4'' <i>R</i> )-4''-deoxy-4''-(methylamino)avermectin $B_1$ benzoate (salt)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| CAS Registry Number                  | 155569-91-8 (formerly 137512-74-4)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| End-use product/EP                   | Proclaim® Insecticide; EPA Reg. No. 100-904; 5% SG formulation<br>Enfold™ Insecticide; EPA Reg. No. 100-RURR; 5% WG formulation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Chemical Class                       | Avermectin insecticide                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Known Impurities of Concern          | None                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |

### 3.2 Physical/Chemical Characteristics

Emamectin benzoate is a solid at room temperature with a low vapor pressure ( $3.0 \times 10^{-8}$  mm Hg at 21°C); thus, any losses due to volatilization/sublimation are expected to be minimal.

Emamectin benzoate, the 8,9-Z isomer, AB, MFB, and FAB are expected to be persistent and relatively immobile in the environment due to a high degree of sorption to soil particles ( $K_{OC}$  from 25,363 to 730,000). Based upon fate data, significant concentrations of parent or formed degradates of toxicological concern are not expected to leach into groundwater.

Refer to a Table of Physicochemical Properties in Appendix B.

### 3.3 Pesticide Use Patterns

#### Cucurbits

IR-4 is proposing use of Proclaim® Insecticide (EPA Reg. No. 100-904), a 5% water-soluble granule (SG) formulation of emamectin benzoate, on the cucurbit vegetable group for the control of armyworms, cabbage looper, corn earworm, melon worm, rindworms, tobacco budworm, pickleworm, and *Liriomyza* leaf miners.

Proclaim® Insecticide may be applied as a foliar spray via aircraft (except in New York State) or groundboom. Chemigation is prohibited. For high pest infestations, the maximum single application rate is 4.8 oz/A (0.015 lb ai/A). Applications may be repeated at a 7-day interval to maintain control, up to a maximum seasonal application rate of 28.8 oz/A (0.090 lb ai/A/season). The preharvest interval (PHI) is 6 days. The REI on the proposed label is 12 hours.



**Table 3.3.1. Summary of Directions for Use of Emamectin Benzoate on Cucurbits.**

| Applic. Timing, Type, and Equip.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Formulation [EPA Reg. No.]            | Applic. Rate (lb ai/A) | Max. No. Applic. per Season | Max. Seasonal Applic. Rate (lb ai/A) | PHI <sup>1</sup> (days) | Use Directions and Limitations                                                                                                                                                                                                                                                                                                                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|------------------------|-----------------------------|--------------------------------------|-------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Vegetable, Cucurbit, Group 9: Chayote (fruit); Chinese waxgourd (Chinese preserving melon); citron melon; cucumber; gherkin; gourd, edible (includes hyotan, cucuzza); hechima; Chinese okra; <i>Momordica</i> spp. (includes balsam apple, balsam pear, bitter melon, Chinese cucumber); muskmelon (hybrids and/or cultivars of <i>Cucumis melo</i> - includes true cantaloupe, cantaloupe, casaba, Crenshaw melon, golden pershaw melon, honeydew melon, honey balls, mango melon, Persian melon, pineapple melon, Santa Claus melon, and snake melon); pumpkin; squash, summer (includes crookneck squash, scallop squash, straightneck squash, vegetable marrow, zucchini); squash, winter (includes butternut squash, calabaza, hubbard squash, acorn squash, spaghetti squash); watermelon (includes hybrids and/or varieties of <i>Citrullus lanatus</i> ). |                                       |                        |                             |                                      |                         |                                                                                                                                                                                                                                                                                                                                                |
| Postemergence, Broadcast, Foliar, Ground or aerial equipment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Proclaim® Insecticide 5% SG [100-904] | 0.0094-0.015           | NS <sup>2</sup>             | 0.090                                | 6                       | <p>Begin applications when larvae are first observed; repeat applications at a minimum RTI<sup>3</sup> of 7 days.</p> <p>Apply in a minimum of 10 gallons of water/A when using either ground or aerial equipment.</p> <p>Use of a penetrating type of spray adjuvant is recommended; use of a sticker/binder type adjuvant is prohibited.</p> |

<sup>1</sup> PHI = preharvest interval.<sup>2</sup> NS = not stated.<sup>3</sup> RTI = retreatment interval.

The following restrictions appear on the accepted Proclaim® Insecticide label (dated 1/26/10): (1) application through any type of irrigation system is prohibited; (2) for applications to vegetables, make no more than two sequential applications, then rotate to another insecticide with a different mode of action; (3) for applications to vegetables, do not use Proclaim in greenhouses, nurseries, in plant propagation houses, or on any plants grown for use as transplants; (4) do not apply with aircraft in NY state; and (5) there are no rotational crop plant-back restrictions for emamectin benzoate.

#### Outdoor-Grown Ornamental Plants in Commercial Nursery Production

Syngenta is proposing use of Endfold™ Insecticide (EPA Reg. No. 100-RURR), a 5% water-dispersible granule formulation of emamectin benzoate, on outdoor-grown ornamental plants in commercial nursery production for the control of the larval stages (worms/caterpillars) of several lepidopteran species and suppression of Liriomyza leafminer, Tetranychid mites, and pear psylla. It is a selective insecticide for use on herbaceous and woody ornamental plants grown outdoors (in containers or in the ground) in commercial nursery production. Woody ornamentals include



(but are not limited to) shrubs, non-bearing fruit and nut trees, Christmas trees, forest seedlings, and shade trees.

Enfold™ Insecticide may be applied as a foliar spray via groundboom, airblast, or aircraft (except in New York State). Chemigation is prohibited. For high pest infestations, the maximum single application rate is 4.8 oz/A (0.015 lb ai/A). Applications may be repeated at a 7- to 14- day interval to maintain control, up to a maximum seasonal application rate of 28.8 oz/A (0.090 lb ai/A/season). The REI on the proposed label is 12 hours.

| <b>Table 3.3.2. Use Profile for Proposed Emamectin Benzoate Use on Outdoor-Grown Ornamentals.</b>               |                              |                                 |               |
|-----------------------------------------------------------------------------------------------------------------|------------------------------|---------------------------------|---------------|
| <i>Enfold™ Insecticide</i><br>EPA Reg. No. 100-RURR<br><i>water dispersible granule (WG), 5.0% ai by weight</i> |                              |                                 |               |
| Use Site                                                                                                        | Application Equipment        | Single Maximum Application Rate |               |
|                                                                                                                 |                              | oz/A                            | lb ai/A       |
| Outdoor Ornamentals<br>(Ground or Container)                                                                    | Groundboom, Airblast, Aerial | 2.4-4.8                         | 0.00075-0.015 |

### 3.4 Anticipated Exposure Pathways

The Registration Division has requested an assessment of human health risk to support the proposed new uses of emamectin benzoate on cucurbit vegetables and on outdoor-grown ornamental plants in commercial nursery production. Humans may be exposed to emamectin benzoate in food and drinking water, since emamectin benzoate may be applied directly to growing crops and application may result in emamectin benzoate reaching surface and ground water sources of drinking water. There are no residential uses of emamectin benzoate as explained in Section 6.0, so there is not likely to be exposure in residential or non-occupational settings. In an occupational setting, applicators may be exposed while handling the pesticide prior to application, as well as during application. There is a potential for post-application exposure for workers re-entering treated fields.

This risk assessment considers all of the aforementioned exposure pathways based on the proposed new uses of emamectin benzoate, but also considers the existing uses as well, particularly for the dietary exposure assessment.

### 3.5 Consideration of Environmental Justice

Potential areas of environmental justice concerns, to the extent possible, were considered in this human health risk assessment, in accordance with U.S. Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," (<http://www.eh.doe.gov/oeпа/guidance/justice/eo12898.pdf>).



As a part of every pesticide risk assessment, OPP considers a large variety of consumer subgroups according to well-established procedures. In line with OPP policy, HED estimates risks to population subgroups from pesticide exposures that are based on patterns of that subgroup's food and water consumption, and activities in and around the home that involve pesticide use in a residential setting. Extensive data on food consumption patterns are compiled by the US Department of Agriculture (USDA) under the National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA), and are used in pesticide risk assessments for all registered food uses of a pesticide. These data are analyzed and categorized by subgroups based on age, season of the year, ethnic group, and region of the country. Additionally, OPP is able to assess dietary exposure to smaller, specialized subgroups and exposure assessments are performed when conditions or circumstances warrant. Whenever appropriate, non-dietary exposures based on home use of pesticide products and associated risks for adult applicators and for toddlers, youths, and adults entering or playing on treated areas post-application are evaluated. Further considerations are currently in development as OPP has committed resources and expertise to the development of specialized software and models that consider exposure to bystanders and farm workers as well as lifestyle and traditional dietary patterns among specific subgroups.

#### 4.0 Hazard Characterization and Dose-Response Assessment

Reference: *EMAMECTIN - 3<sup>rd</sup> Report of the Hazard Identification Assessment Review Committee* - (Memo, HED TXR. No. 0051605, 03/5/2003).

No new toxicity and/or metabolism data have been reviewed since the last risk assessment. This assessment includes summaries of prior assessments.

Details of the toxicology of emamectin, including executive summaries of the toxicity studies, are available in the HED memo, *EPA ID#: 000618-RNI: Application for Establishment of Permanent Tolerance for the Use of Emamectin on Cole Crops and Leafy Vegetables*, G. Reddy, 06/30/98. A summary of the toxicology profile for emamectin is presented in Appendix A.

#### 4.1 Summary of Toxicological Effects

Emamectin is a member of the naturally derived complex of 16-membered macrocyclic lactones, which include abamectin, avermectin, and ivermectin. On the cellular level, a member of this group of compounds has been shown to act by binding to gamma-aminobutyric acid (GABA) gated chloride channels at two different sites, a high affinity binding site that activates the channel and a low affinity site that blocks the channel (Pong et al., 1982; Huang and Casida, 1997; and Dawson et al., 2000). GABA plays a critical role in nervous system development through both non-synaptic (Represa and Ben-Ari, 2005) and synaptic (Nguyen et al., 2001) mechanisms. Consequently, emamectin may have the potential to influence GABA-mediated events important to brain development. Within the mammalian brain, a member of this class of



compound (abamectin) has been shown to have widespread binding but particularly abundant in the cerebellum (Wang and Pong, 1982). Through action on the enteric nervous system and induction of longitudinal rhythmic contractions in the isolated ileum, emamectin, like abamectin, may therefore influence GABA-mediated regulation of metabolism, food intake and body weight at multiple sites (Kerr and Ong, 1986, Meister, 2007). Although GABA receptor mediated neurotoxicity is a solid hypothesis, data in mammalian preparations linking alterations in GABA receptor function to disruptions in neuronal excitability *in vitro* and *in vivo*, and ultimately adverse outcome are currently lacking.

Integral to its mechanism of action in mammals, this class of compounds is also a substrate for P-glycoprotein (P-gp). P-glycoprotein is a member of the ATP binding cassette transporter proteins, which reside in the plasma membrane and function as a transmembrane efflux pump, moving xenobiotics from the intracellular to the extracellular domain against a steep concentration gradient with ATP-hydrolysis providing the energy for active transport (Marzolini et al., 2004). P-gp is found in the canallicular surface of hepatocytes, the apical surface of proximal tubular cells in the kidneys, brush border surface of enterocytes, luminal surface of blood capillaries of the brain (blood brain barrier), placenta, ovaries, and the testes. As an efflux transporter, P-gp acts as a protective barrier to keep xenobiotics out of the body by excreting them into bile, urine, and intestinal lumen and prevents accumulation of these compounds in the brain and gonads, as well as the fetus. Therefore, some test animals, in which genetic polymorphisms compromise P-gp expression, are particularly susceptible to abamectin or emamectin-induced neurotoxicity (Lankas et al., 1997). An example is the CF-1 mouse. Some CF-1 mice are deficient in P-gp and are found to be highly sensitive to the neurotoxicity of abamectin. A very small population of humans is also found to be deficient of ATP binding cassette (ABC) transporter proteins due to polymorphism in the gene encoding ABC transporter proteins (Dubin-Johnson Syndrome) (S. Habashi, 2006, A.T. Niles, 2007). In addition, collie dogs have been known to be deficient in P-gp (R. Kerb, 2005).

Consistent with the mode of action, the main target organ for emamectin is the nervous system; clinical signs (tremors, ptosis, ataxia, and hunched posture) and neuropathology (neuronal degeneration in the brain and in peripheral nerves, muscle fiber degeneration) were found in most of the emamectin studies in rats, dogs and mice. The dose-response curve was very steep in several studies (most notably with CF-1 mice and dogs), with severe effects (morbid sacrifice and neuropathology) sometimes seen at the LOAELs (0.1 mg/kg/day with a no observable adverse effect level (NOAEL) of 0.075 mg/kg/day). Although no increased sensitivity was seen in developmental toxicity studies in rats and rabbits, increased qualitative and/or quantitative sensitivity of rat pups was seen in the reproductive toxicity and in the developmental neurotoxicity studies. In the reproduction study, whole body tremors, hind limb extension, and hind limb splay were seen in the F<sub>1</sub> and F<sub>2</sub> pups while these clinical signs were not seen in F<sub>0</sub> parental animals at similar dose levels. In addition, a greater incidence of decreased fertility was seen in the F<sub>1</sub> parental females than in the F<sub>0</sub> females. In the developmental neurotoxicity study, no maternal effect was seen at the highest dose tested whereas dose-related decrease in open-field motor activity was seen in the mid-dose on PND 17. Body tremors, hind-limb extension,



and auditory startle were also found in the high dose pups.

A degree-of-concern analysis was conducted to determine whether or not an additional safety factor is needed to account for the increased susceptibility in pups; it was concluded that the degree-of-concern was low for both 2-generation reproduction and developmental neurotoxicity studies. The reasons are as follows:

- For the 2-generation reproduction study, (1) there was a clear NOAEL for the offspring toxicity, (2) effects unique to offspring (decreased fertility in F<sub>1</sub> adults, and clinical signs [tremors and hind limb extensions during and following lactation]) were seen at the same dose that caused parental systemic toxicity (decreased body weight gain and histopathological lesions in the brain and spinal cord), and (3) the decreased fertility seen in F<sub>1</sub> adults might have been due to histopathological lesions in the brain and central nervous system (seen in both F<sub>0</sub> and F<sub>1</sub> generations), rather than due to a direct effect on the reproductive system.
- For the developmental neurotoxicity study, (1) although multiple offspring effects (including decreased pup body weight, head and body tremors, hindlimb extension and splay, changes in motor activity and auditory startle) were seen at the highest dose (3.6 mg/kg/day), and no maternal effects were seen at any dose, there was a clear NOAEL for offspring toxicity at the low dose, and (2) the offspring LOAEL (at the mid dose) is based on a single effect seen on only one day (decreased motor activity on PND 17) and no other offspring toxicity was seen at the LOAEL.

The carcinogenicity and mutagenicity studies provide no indication that emamectin is carcinogenic or mutagenic. Emamectin is classified as “not likely to be carcinogenic to humans.” A toxicity profile for emamectin is presented in Appendix A.

The acute toxicity studies indicate that emamectin has low to moderate acute toxicity by the oral, dermal and inhalation routes. It is not irritating to the skin, nor is it a dermal sensitizer. However, depending on the technical test substance, abamectin has been shown to be a severe eye irritant. A recent (as of 2008) submission of acute toxicity six-pack tests performed on a new technical product (Emamectin Benzoate Technical II, EPA Reg. No. 100-1270) resulted in new toxicity category assignments. Specifically, the toxicity category for inhalation changed from Category IV to Category II. Relevant to the REI, the eye irritation study changed from Category I to Category III. HED had concern for the possibility that a change in manufacturers and technical registrations could result in a different acute toxicity outcome, while the technical compound itself had not changed. Detailed information has been submitted which confirms the appropriateness of the REI reduction.

The most recent toxicity endpoints and points of departure for risk assessment were determined by HED in 2003. The available emamectin data show that there is a difference in species sensitivity, and the data suggest the following order: rat NOAELs/LOAELs > dog



NOAELs/LOAELs > mouse NOAELs/LOAELs. The toxicity endpoints and points of departure for risk were selected from the results of the 15-day CF-1 mouse oral toxicity study. No new toxicity studies have been submitted since 2003, and these selections are still valid.

#### **4.2 Safety factor for Infants and Children (FQPA Safety Factor)**

Based on currently available data, HED recommends that the 10X FQPA safety factor be retained for chronic assessments and that a 3X FQPA safety factor is adequate for acute assessments. For inhalation exposure assessment, additional uncertainty factors of 10X for lack of an inhalation toxicity study and of 3X for the steepness of the dose-response curve are to be applied; these are combined with the normal 100X safety factor resulting in the application of a maximal uncertainty factor of 3000X.

The 10X FQPA safety factor has been retained for chronic/long-term and intermediate-term assessments for oral and dermal exposure due to the steepness of the dose-response curve, severity of effects at the LOAEL (death and neuropathology), and the use of a short-term study for long-term risk assessment. (HED did not use a chronic study for the point of departure because the chronic studies were conducted in rats, dogs, and CD-1 mice. The 15-day study employed the CF-1 mice, which do not have the glycoprotein. As a result, the point of departure is protective of all population subgroups.) The steepness of the dose-response curve and the severity of the effects at the LOAEL also are the basis for HED retaining a 3X FQPA safety factor for acute assessments. A 3X FQPA safety factor was judged to be adequate (as opposed to a 10X) for the following reasons: (1) A NOAEL was established in the 15-day neurotoxicity CF-1 mouse study used to determine the acute toxicity endpoint for risk assessment; (2) Although the effects of concern are seen after repeated dosing, the NOAEL here is used for a single exposure risk assessment; and (3) The most sensitive endpoint in the most sensitive species is selected.

##### **4.2.1 Completeness of the Toxicology Database**

The toxicology database used to assess pre- and post-natal exposure to emamectin is considered adequate. However, under the current data requirement guidelines, an immunotoxicity study and an inhalation toxicity study are required.

##### Immunotoxicity study

The risk assessment team evaluated subchronic, chronic, carcinogenicity, developmental and reproduction studies as well as acute and subchronic neurotoxicity studies for any effects which might indicate that emamectin induced changes in the organs generally associated with immunological toxicity. In the studies evaluated, only the 14-week oral toxicity study in dogs showed an increase in the incidence of thymus atrophy at 1 mg/kg/day. In the 1-year feeding study in the dog, thymus atrophy was not reported at similar dose levels tested. Currently, the point of departure for risk assessment is 0.075 mg/kg/day, which is more than 10x less than the



dose where thymus atrophy had been reported. At this time, the acute and chronic reference doses (RfD's) are 0.00025 mg/kg/day and 0.000075 mg/kg/day, respectively; therefore, database uncertainty factor is not necessary to account for the lack of an immunotoxicity study at this time.

#### Inhalation toxicity study

Since no inhalation studies are available, the Agency selected an oral NOAEL of 0.075 mg/kg/day established in the 15-day neurotoxicity study in mice for inhalation risk assessments. Therefore, a 28-day subchronic inhalation study is required for the reasons that the inhalation study (1) may provide route specific effects (route of entry effects) and (2) may result in changes to the endpoints and how the risks are quantified. In addition, the acute inhalation toxicity category for emamectin is II, and in a 5-day preliminary inhalation study, histopathological changes were found in the respiratory tract at all dose levels (1 µg/L to 125 µg/L). The study should be performed using the CF-1 mouse. In 2006, the registrant and the Agency held several meetings to discuss the conduct of the 28-day inhalation toxicity study (specifically the strain of test animal to be used). At this time, the Agency still maintains that this study should be conducted in the most sensitive strain of mice (CF-1 mice). A 10x uncertainty factor is recommended for lack of an inhalation toxicity study.

#### **4.2.2 Evidence of Neurotoxicity**

Following emamectin exposure, neurotoxicity has been seen in multiple studies with several species of test animals.

#### **4.2.3 Evidence of Sensitivity/Susceptibility in the Developing or Young Animal**

Although no increased sensitivity was seen in developmental toxicity studies in rats and rabbits, increased qualitative and/or quantitative sensitivity of rat pups was seen in the reproductive toxicity study and in the developmental neurotoxicity study (see details in Section 4.1: Summary of Toxicological Effects).

#### **4.2.4 Residual Uncertainty in the Exposure Database**

The assessment for food incorporates somewhat refined anticipated residue estimates for most commodities that were derived from field trial data and percent crop treated (% CT) data. Monitoring data were used for apples in the acute assessment. The availability and use of more monitoring data and of food preparation-reduction factors for washing, cooking, etc. may have resulted in a more refined estimate of dietary exposure. Therefore, exposures to residues in food are not expected to be underestimated.

The dietary drinking water assessment utilizes water concentration values generated by model and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations which will not likely be underestimated.

Residential exposure is not expected from the established and proposed uses. Residential exposures from commercial nursery production are expected to be negligible because the emamectin is expected to dissipate by the time the plant moves from a nursery, through a retail store, to the consumer.

#### 4.3 Toxicity Endpoint and Point of Departure Selections

There have been no changes to the prior dose-response assessment. There have been no changes to the prior recommendations for combining routes of exposure and/or cancer classification.

The points of departure, uncertainty factors, and toxicity endpoints are presented in Tables 4.3.1 and 4.3.2.

| <b>Exposure/Scenario</b>          | <b>Point of Departure</b>                                                                                                                                     | <b>Uncertainty/FQPA Safety Factors</b>                          | <b>RfD, PAD, Level of Concern for Risk Assessment</b>             | <b>Study and Toxicological Effects</b>                                                                                                                                                                        |
|-----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|-------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Acute Dietary (All Populations)   | NOAEL = 0.075 mg/kg/day                                                                                                                                       | UF <sub>A</sub> = 10x<br>UF <sub>H</sub> = 10x<br>FQPA SF = 3x  | Acute RfD = 0.00025 mg/kg/day<br><br>aPAD = 0.00025 mg/kg/day     | <b>15-day mouse</b><br>LOAEL = 0.1 mg/kg/day based on tremors on day 3 of dosing. At the next higher dose (0.3 mg/kg/day), tremors were seen at day 2 of treatment.                                           |
| Chronic Dietary (All Populations) | NOAEL = 0.075 mg/kg/day                                                                                                                                       | UF <sub>A</sub> = 10x<br>UF <sub>H</sub> = 10x<br>FQPA SF = 10x | Chronic RfD = 0.000075 mg/kg/day<br><br>cPAD = 0.000075 mg/kg/day | <b>15-day mouse</b><br>LOAEL = 0.1 mg/kg/day based on moribund sacrifices, clinical signs of neurotoxicity, decreases in body weight and food consumption and histopathological lesions in the sciatic nerve. |
| Cancer (oral, dermal, inhalation) | Classification: "Not likely to be Carcinogenic to Humans" based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies. |                                                                 |                                                                   |                                                                                                                                                                                                               |

<sup>1</sup>Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = FQPA Safety Factor. (The 10X FQPA safety factor for chronic/long-term and intermediate-term assessments is to account for the steepness of the dose-response curve, severity of effects at the LOAEL (death and neuropathology), and the use of a short-term study for intermediate-term risk assessment. The 3X FQPA safety factor for acute assessments is to account for steepness of the dose-response curve and the severity of the effects at the LOAEL.) PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

<sup>2</sup>Dermal absorption of 1.8% is assumed.



**Table 4.3.2 Summary of Toxicological Doses and Endpoints for Emamectin Benzoate for Use in Occupational Human Health Risk Assessments<sup>1,2</sup>**

| Exposure/Scenario                         | Point of Departure                                                                                                                                            | Uncertainty Factors                                                     | Level of Concern for Risk Assessment | Study and Toxicological Effects                                                                                                                                                                               |
|-------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|--------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Dermal Short-Term (1-30 days)             | NOAEL = 0.075 mg/kg/day (dermal absorption rate = 1.8%)                                                                                                       | UF <sub>A</sub> = 10x<br>UF <sub>H</sub> = 10x<br>FQPA = 3x             | Occupational LOC for MOE = 300       | <b>15-day mouse</b><br>LOAEL = 0.1 mg/kg/day based on moribund sacrifices, clinical signs of neurotoxicity, decreases in body weight and food consumption and histopathological lesions in the sciatic nerve. |
| Dermal Intermediate-Term (1-6 months)     | NOAEL = 0.075 mg/kg/day (dermal absorption rate = 1.8%)                                                                                                       | UF <sub>A</sub> = 10x<br>UF <sub>H</sub> = 10x<br>FQPA = 10x            | Occupational LOC for MOE = 1000      | <b>15-day mouse</b><br>LOAEL = 0.1 mg/kg/day based on moribund sacrifices, clinical signs of neurotoxicity, decreases in body weight and food consumption and histopathological lesions in the sciatic nerve. |
| Inhalation Short-Term (1-30 days)         | NOAEL = 0.075 mg/kg/day (assumed equivalent to oral absorption)                                                                                               | UF <sub>A</sub> = 10x<br>UF <sub>H</sub> = 10x<br>UF <sub>m</sub> = 30x | Occupational LOC for MOE = 3000      | <b>15-day mouse</b><br>LOAEL = 0.1 mg/kg/day based on moribund sacrifices, clinical signs of neurotoxicity, decreases in body weight and food consumption and histopathological lesions in the sciatic nerve. |
| Inhalation Intermediate-Term (1-6 months) | NOAEL = 0.075 mg/kg/day (assumed equivalent to oral absorption)                                                                                               | UF <sub>A</sub> = 10x<br>UF <sub>H</sub> = 10x<br>UF <sub>m</sub> = 30x | Occupational LOC for MOE = 3000      | <b>15-day mouse</b><br>LOAEL = 0.1 mg/kg/day based on moribund sacrifices, clinical signs of neurotoxicity, decreases in body weight and food consumption and histopathological lesions in the sciatic nerve. |
| Cancer (oral, dermal, inhalation)         | Classification: "Not likely to be Carcinogenic to Humans" based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies. |                                                                         |                                      |                                                                                                                                                                                                               |

<sup>1</sup>Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies). UF<sub>m</sub> = modifying factor: the 30X consisted of 3X to account for the steepness of the dose-response curve, severity of effects at the LOAEL (death and neuropathology) and 10 x for lack of an inhalation toxicity study. MOE = margin of exposure. LOC = level of concern.

<sup>2</sup>Dermal absorption of 1.8% is assumed.

### Endocrine Disruption

As required by FIFRA and FFDCA, EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its most recent registration decision, EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA section 408(p), emamectin benzoate is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a “naturally occurring estrogen, or other such endocrine effects as the Administrator may designate.” The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA section 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. Emamectin benzoate is not among the group of 58 pesticide active ingredients on the initial list to be screened under the EDSP. Accordingly, as part of registration review, EPA will issue future EDSP orders/data call-ins, requiring the submission of EDSP screening assays for emamectin benzoate. For further information on the status of the EDSP, the policies and procedures, the list of 67 chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit our website: <http://www.epa.gov/endo/>.

## **5.0 Dietary Exposure and Risk Assessment**

### **5.1 Residues of Concern Summary and Rationale**

Plants: The major metabolite identified in lettuce, cabbage, and sweet corn treated with [<sup>14</sup>C]emamectin B<sub>1a</sub> (MAB<sub>1a</sub>) was the parent MAB<sub>1a</sub>. The isomer 8,9-ZB<sub>1a</sub> and the



metabolites/degradates AB<sub>1a</sub>, MFB<sub>1a</sub>, and FAB<sub>1a</sub> were identified at <5% of the TRR. MAB<sub>1a</sub> initially degrades rapidly to a large number of residues of MAB<sub>1a</sub>-like structures, nearly all contributing only a small amount to the total residue; these initial degradates undergo further degradation to yield a very complex residue. These degradations are probably a result of photolysis, and after this photolytic process, these degradates can be fragmented and incorporated into natural plant constituents.

**Ruminants:** The parent compounds, emamectin (MAB<sub>1a</sub> + MAB<sub>1b</sub>), are the only major residue found in goat milk, fat, meat and meat byproducts. However, the analytical method for the determination of residues of emamectin and its metabolites in livestock commodities cannot distinguish between the parent compounds and its metabolites, 8,9-ZMA (8,9-ZB<sub>1a</sub> + 8,9-ZB<sub>1b</sub>). In the absence of toxicity data, the metabolites 8,9-ZMA (8,9-ZB<sub>1a</sub> + 8,9-ZB<sub>1b</sub>) are assumed to be of comparable toxicity to the parent.

**Drinking water:** Parent and degradates (refer to Table 5.1) were included in the drinking water assessment for emamectin benzoate. The degradates are assumed to be of equal or lesser toxicity to that of the parent compound.

The residues of concern for the dietary risk assessment and the tolerance expression are summarized in Table 5.1.

| Table 5.1. Summary of Metabolites and Degradates to be included in the Risk Assessment and Tolerance Expression |                  |                                                                                                                                                                                                                        |                                                                                                                                                                                                                        |
|-----------------------------------------------------------------------------------------------------------------|------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Matrix                                                                                                          |                  | Residues included in Risk Assessment                                                                                                                                                                                   | Residues included in Tolerance Expression                                                                                                                                                                              |
| Plants <sup>1</sup>                                                                                             | Primary Crops    | emamectin (MAB <sub>1a</sub> + MAB <sub>1b</sub> ), the associated 8,9-Z isomers (8,9-ZB <sub>1a</sub> + 8,9-ZB <sub>1b</sub> ), and metabolites/degradates AB <sub>1a</sub> , MFB <sub>1a</sub> and FAB <sub>1a</sub> | emamectin (MAB <sub>1a</sub> + MAB <sub>1b</sub> ), the associated 8,9-Z isomers (8,9-ZB <sub>1a</sub> + 8,9-ZB <sub>1b</sub> ), and metabolites/degradates AB <sub>1a</sub> , MFB <sub>1a</sub> and FAB <sub>1a</sub> |
|                                                                                                                 | Rotational Crops | Same as for primary crops                                                                                                                                                                                              | Same as for primary crops                                                                                                                                                                                              |
| Livestock <sup>1</sup>                                                                                          | Ruminant         | emamectin (MAB <sub>1a</sub> + MAB <sub>1b</sub> ) and its 8,9-Z isomers (8,9-ZB <sub>1a</sub> and 8,9-ZB <sub>1b</sub> )                                                                                              | emamectin (MAB <sub>1a</sub> + MAB <sub>1b</sub> ) and its 8,9-Z isomers (8,9-ZB <sub>1a</sub> and 8,9-ZB <sub>1b</sub> )                                                                                              |
|                                                                                                                 | Poultry          | Not applicable                                                                                                                                                                                                         | Not applicable                                                                                                                                                                                                         |
| Drinking Water <sup>2</sup>                                                                                     |                  | emamectin (MAB <sub>1a</sub> + MAB <sub>1b</sub> ), the associated 8,9-Z isomers (8,9-ZB <sub>1a</sub> + 8,9-ZB <sub>1b</sub> ), and metabolites/degradates                                                            | Not Applicable                                                                                                                                                                                                         |

<sup>1</sup> TXR#0050315, Manying Xue, 1/28/02

<sup>2</sup> TXR#0050315 (Manying Xue, 1/28/02) indicated that drinking water residues should be emamectin (MAB<sub>1a</sub> + MAB<sub>1b</sub>), the associated 8,9-Z isomers (8,9-ZB<sub>1a</sub> + 8,9-ZB<sub>1b</sub>), and the metabolites/degradates AB<sub>1a</sub>, MF B<sub>1a</sub>, and FAB<sub>1a</sub>. DP#402307 (T. Downen, 5/30/12) indicated that the drinking water analytes included emamectin and the following four degradates: (8,9-Z)-4"-epimethylamino-4"-deoxy avermectin B1 (8,9 ZMA isomer); 4"-epiamino-4"-deoxyavermectin B1 (AB); avermectin B1 monosaccharide; and 4"-epi-(N-formyl)-4"-deoxyavermectin B1 (FAB).

## 5.2 Food Residue Profile

**Crop Field Trials:** IR-4 submitted crop field trial data on cucumber, squash, and cantaloupe in support of the proposed use of the 5% SG formulation of emamectin benzoate on cucurbit vegetables. The residue data are summarized in Table 5.2 below. All residues are <0.02 ppm.

| Table 5.2. Summary of Residue Data from Crop Field Trials with Emamectin Benzoate (SG Formulation). |                              |               |                                      |             |             |                   |                   |        |       |           |
|-----------------------------------------------------------------------------------------------------|------------------------------|---------------|--------------------------------------|-------------|-------------|-------------------|-------------------|--------|-------|-----------|
| Commodity                                                                                           | Total App. Rate<br>(lb ai/A) | PHI<br>(days) | Combined Residues (ppm) <sup>1</sup> |             |             |                   |                   |        |       |           |
|                                                                                                     |                              |               | n                                    | Sample Min. | Sample Max. | LAFT <sup>2</sup> | HAFT <sup>2</sup> | Median | Mean  | Std. Dev. |
| Vegetable, Cucurbit, Group 9 (proposed use = 0.09 lb ai/A total application rate, 7-day PHI)        |                              |               |                                      |             |             |                   |                   |        |       |           |
| Cucumber                                                                                            | 0.077-0.092                  | 6-8           | 8                                    | <0.02       | <0.02       | 0.02              | 0.02              | 0.02   | 0.02  | NA        |
| Summer Squash                                                                                       | 0.090-0.093                  | 6-8           | 8                                    | <0.02       | <0.02       | 0.02              | 0.02              | 0.02   | 0.02  | NA        |
| Cantaloupe                                                                                          | 0.089-0.092                  | 6-8           | 10                                   | <0.006      | <0.0081     | 0.006             | 0.008             | 0.006  | 0.006 | 0.001     |

<sup>1</sup> Combined residues include total emamectin (MAB<sub>1a</sub> and MAB<sub>1b</sub>), its 8,9-Z isomers (8,9-ZB<sub>1a</sub> and 8,9-ZB<sub>1b</sub>), and metabolites/degradates AB<sub>1a</sub>, MFB<sub>1a</sub>, and FAB<sub>1a</sub>. Except for sample min/max, values reflect per trial averages; n = no. of field trials. For calculation of median, mean, and standard deviation, the LOQ (0.02 ppm for cucumber and squash and 0.006 ppm for cantaloupe) was used for any results reported as <LOQ. NA = Not applicable.

<sup>2</sup> LAFT = lowest average field trial; HAFT = highest average field trial.

The submitted cucumber, summer squash, and cantaloupe crop field trial data are adequate and fulfill the field trial requirements for the cucurbit vegetable group 9. The studies reflect the maximum proposed use pattern for cucurbit vegetables, and the number and locations of the field trials are in accordance with OCSPP 860.1500 for each crop. An acceptable method was used for residue quantitation, and the data are supported by adequate storage stability data.

The available residue data are sufficient for establishing a tolerance of 0.02 ppm for vegetable, cucurbit, group 9 in association with the requested registration of the 5% SG formulation on cucurbit vegetables.

**Processing Studies:** There are no regulated processed commodities associated with cucurbit vegetables.

**Storage Stability:** Adequate storage stability data are available to support the cucurbit vegetable field trial studies. No corrections for residue decline during storage are needed.



*Meat, Milk, Poultry, and Eggs:* There are no livestock feedstuffs associated with use on cucurbit vegetables.

*Rotational Crops:* Total radioactive residues in a confined rotational crop study after application of [ $^{14}\text{C}$ ]MAB<sub>1a</sub> were <0.01 ppm in/on immature and mature head lettuce, carrots, and barley from all plantback intervals (30, 120/141, and 365 days); only barley straw had residues at >0.01 ppm (0.016 and 0.030 ppm) at the 30- and 141-day plantback intervals. Emamectin and its metabolites were not identified in 30- and 141-DAT (days after treatment) barley straw. There is no indication that emamectin residues of concern would be present in rotational crops at levels  $\geq 0.01$  ppm, and no plantback restrictions are needed on the labels.

### 5.3 Water Residue Profile

The drinking water residues used in the dietary risk assessment were provided by EFED in the following memorandum: "*Amended Drinking Water Assessment for the Proposed Use of Emamectin Benzoate on Outdoor Ornamentals and Group 9 Cucurbit Vegetables*" (Tiffany Downen, 5/30/12, DP#402307) and incorporated directly into this dietary assessment. Water residues were incorporated in the DEEM-FCID into the food categories "water, direct, all sources" and "water, indirect, all sources."

EFED provided EDWCs for the proposed/registered uses of emamectin benzoate including the proposed uses on outdoor ornamentals (EPA Reg. No. 100-RURR) and cucurbit vegetables (EPA Reg. No. 100-904). EDWCs from use on outdoor-grown ornamentals are the highest. Emamectin benzoate residues (parent + degradation products), based on applications made to ornamentals and group 9 cucurbits, are not expected to exceed 0.465  $\mu\text{g/L}$  for the 1 in 10 year daily peak, 0.150  $\mu\text{g/L}$  for the 1 in 10 year annual average, and 0.112  $\mu\text{g/L}$  for the 30 year annual average (Table 5.3).

The Agency identified four degradates of concern based on structural similarity to emamectin benzoate that are formed via photolysis (MARC memo references: D238206, Sept 2, 1997; D255357, Aug 20, 2001; D277085, Aug 20, 2001):

- (8,9-Z)-4"-epimethylamino-4"-deoxy avermectin B1 (8,9 ZMA isomer);
- 4"-epiamino-4"-deoxyavermectin B1 (AB);
- avermectin B1 monosaccharide (MAB); and
- 4"-epi-(N-formyl)-4"-deoxyavermectin B1 (FAB).

These degradates were included in the drinking water assessment for emamectin benzoate and are assumed to be of equal or lesser toxicity to that of the parent compound. The total toxic residues approach is used for determining the environmental fate data parameters for modeling using the *Guidance for Selecting Input Parameters in Modeling the Environmental Fate and Transport of Pesticides*, Version 2.1, October 22, 2009, and the draft *Guidance for Modeling*

Pesticides Total Toxic Residues (TTR), dated May 20, 2009.

| <b>Table 5.3 Summary of Estimated Surface Water and Groundwater Concentrations for Emamectin Benzoate.<sup>a</sup></b> |                                             |                                           |
|------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|-------------------------------------------|
| <b>Scenario</b>                                                                                                        | <b>Surface Water Conc., ppb<sup>b</sup></b> | <b>Groundwater Conc., ppb<sup>c</sup></b> |
| Acute                                                                                                                  | 0.465                                       | $0.54 \times 10^{-3}$                     |
| Chronic (non-cancer)                                                                                                   | 0.150                                       | $0.54 \times 10^{-3}$                     |
| Chronic (cancer)                                                                                                       | 0.112                                       | $0.54 \times 10^{-3}$                     |

<sup>a</sup> Degradates of concern included in the calculation of EDWCs: (8,9-Z)-4"-epimethylamino-4"-deoxy avermectin B1, 4"-epiamino-4"-deoxyavermectin B1, avermectin B1 monosaccharide, and 4"-epi-(N-formyl)-4"-deoxyavermectin B1 (the 8,9 ZMA isomer, AB, MAB, and FAB, respectively).

<sup>b</sup> From the Tier II PRZM-EXAMS - Index Reservoir model. Input parameters are based on the use on ornamentals. Typically, the values generated by the models for drinking water are multiplied by a percent crop area factor (PCA). The PCA accounts for the fact that it is unlikely for any basin to be completely planted to agricultural crops. The PCA adjustment factor is assumed to be 0.87 for the group 9 cucurbit vegetables and 1.0 for the outdoor ornamentals crops as per the PCA guidance.

<sup>c</sup> From the SCI-GROW model. Input parameters are based on the use on ornamentals/group 9 cucurbit vegetables.

<sup>d</sup> "Amended Drinking Water Assessment for the Proposed Use of Emamectin Benzoate on Outdoor Ornamentals and Group 9 Cucurbit Vegetables" (Tiffany Downen, 5/30/12, DP#402307)

## 5.4 Dietary Risk Assessment

### 5.4.1 Description of Residue Data Used in Dietary Assessment

**Acute assessment:** A probabilistic acute dietary exposure assessment was conducted. The anticipated residue estimates, used for most crops, were based on field trial data. Tolerance-level residues were used for tree nuts (including pistachios) and cottonseed oil. Pesticide Data Program (PDP) monitoring data for years 2009 and 2010 were used for apples since apple juice had a significant impact on exposure. DEEM default processing factors were used except for commodities with chemical-specific processing studies. Percent crop treated (% CT) data and percent crop treated data for new crops (PCTn) provided by the Biological and Economic Analysis Division (BEAD) in 2012 were used. The EDWCs of emamectin benzoate were provided by EFED. A drinking water residue distribution based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) modeling of the use on ornamentals was used in the acute assessment.

**Chronic assessment:** A somewhat refined chronic dietary exposure assessment was conducted. The anticipated residue estimates, used for most crops, were single point estimates (averages) based on field trial data. Tolerance-level residues were used for tree nuts (including pistachios) and cottonseed oil. DEEM default processing factors were used except for commodities with chemical-specific processing studies. Percent crop treated data and PCTn data provided by BEAD in 2012 were used. The EDWC of 0.150 µg/L (ppb) for the chronic exposure was based on PRZM/EXAMS modeling of the use on ornamentals, which resulted in the highest chronic EDWC considering all proposed/registered uses.



#### 5.4.2 Percent Crop Treated Used in Dietary Assessment

The following maximum percent crop treated estimates [D401786, Jihad Alsadek, 5/29/12; Screening Level Usage Analysis (SLUA) dated 5/29/12] were used in the acute dietary risk assessment for the following crops that are currently registered for emamectin benzoate: almonds, 2.5%; apples, 20%; broccoli, 20%; cabbage, 25%; cauliflower, 20%; celery, 40%; cotton, 2.5%; lettuce, 20%; pears, 20%; peppers, 15%; spinach, 10%; and tomatoes, 20%.

The following maximum percent crop treated estimates from the SLUA dated 5/29/12 were used in the chronic dietary risk assessment for the following crops that are currently registered for emamectin benzoate: almonds, 1%; apples, 10%; broccoli, 5%; cabbage, 10%; cauliflower, 10%; celery, 25%; cotton, 1%; lettuce, 10%; pears, 5%; peppers, 5%; spinach, 5%; and tomatoes, 10%.

The following percent crop treated estimates for new crops (PCTn) (D403689, Jihad Alsadek, 8/21/12) were used in the acute dietary risk assessment: cantaloupe, 51%; cucumber, 26%; squash, 46%; and watermelon, 21%.

The following PCTn estimates (D403689, Jihad Alsadek, 8/21/12) were used in the chronic dietary risk assessment: cantaloupe, 40%; cucumber, 14%; squash, 29%; and watermelon, 19%.

#### 5.4.3 Acute Dietary Risk Assessment

The general U.S. population and the following population subgroups were assessed: all infants (<1 year old), children 1-2 years old, children 3-5 years old, children 6-12 years old, youth 13-19 years old, adults 20-49 years old, females 13-49 years old, and adults 50+ years old.

As shown in Table 5.4.6.1, the most highly exposed subgroup was children 1-2 years old, with exposure of 60% of the aPAD. The risk estimates for all populations assessed were below the level of concern.

The acute assessment is a probabilistic assessment which incorporates anticipated residue estimates for most commodities that were derived from field trial data. Percent crop treated data were used for some new and registered crops. Monitoring data were used for apples in the acute assessment since apple juice had a significant impact on exposure. The use of more monitoring data and of food preparation-reduction factors for washing, cooking, etc. may have resulted in more refined estimates of dietary exposure. More highly refined analyses are not needed at this time since the risk estimates are below HED's level of concern.



#### 5.4.4 Chronic Dietary Risk Assessment

The general U.S. population and the following population subgroups were assessed: all infants (<1 year old), children 1-2 years old, children 3-5 years old, children 6-12 years old, youth 13-19 years old, adults 20-49 years old, females 13-49 years old, and adults 50+ years old.

As shown in Table 5.4.6.2, the most highly exposed subgroup was all infants less than one year old, with exposure of 16% of the cPAD. The risk estimates for all populations assessed were below HED's level of concern.

The chronic assessment for food is a somewhat refined assessment which incorporates anticipated residue estimates for most commodities that were derived from field trial data. Percent crop treated data were used for some new and registered crops. The use of more monitoring data and of food preparation-reduction factors for washing, cooking, etc. may have resulted in more refined estimates of dietary exposure. More highly refined analyses are not needed at this time since the risk estimates are below HED's level of concern.

#### 5.4.5 Cancer Dietary Risk Assessment

Emamectin benzoate is classified as "not likely to be carcinogenic to humans" based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.

#### 5.4.6 Summary Tables

The results of the acute dietary (food + drinking water) exposure analysis at the 95<sup>th</sup>, 99<sup>th</sup>, and 99.9<sup>th</sup> percentiles of exposure are reported in Table 5.4.6.1 below. The acute dietary exposure estimates for food and drinking water using the ornamentals scenario for drinking water are below HED's level of concern at the 99.9<sup>th</sup> percentile of exposure for the general U.S. population and all population subgroups (36% of the aPAD for the general U.S. population and 60% of the aPAD for children 1-2 years old, the most highly exposed population subgroup).

| Table 5.4.6.1 Results of Acute Dietary (Food and Drinking Water) Exposure Analysis Using DEEM FCID |                     |                             |           |                             |           |                               |           |
|----------------------------------------------------------------------------------------------------|---------------------|-----------------------------|-----------|-----------------------------|-----------|-------------------------------|-----------|
| Population Subgroup                                                                                | aPAD<br>(mg/kg/day) | 95 <sup>th</sup> Percentile |           | 99 <sup>th</sup> Percentile |           | 99.9 <sup>th</sup> Percentile |           |
|                                                                                                    |                     | Exposure<br>(mg/kg/day)     | %<br>aPAD | Exposure<br>(mg/kg/day)     | %<br>aPAD | Exposure<br>(mg/kg/day)       | %<br>aPAD |
| General U.S. Population                                                                            | 0.00025             | 0.000019                    | 7.4       | 0.000038                    | 15        | 0.000091                      | 36        |
| All Infants (< 1 year old)                                                                         |                     | 0.000037                    | 15        | 0.000070                    | 28        | 0.000138                      | 55        |
| Children 1-2 years old                                                                             |                     | 0.000038                    | 15        | 0.000074                    | 29        | <b>0.000151</b>               | <b>60</b> |
| Children 3-5 years old                                                                             |                     | 0.000028                    | 11        | 0.000059                    | 23        | 0.000135                      | 54        |



| Table 5.4.6.1 Results of Acute Dietary (Food and Drinking Water) Exposure Analysis Using DEEM FCID |                     |                             |           |                             |           |                               |           |
|----------------------------------------------------------------------------------------------------|---------------------|-----------------------------|-----------|-----------------------------|-----------|-------------------------------|-----------|
| Population Subgroup                                                                                | aPAD<br>(mg/kg/day) | 95 <sup>th</sup> Percentile |           | 99 <sup>th</sup> Percentile |           | 99.9 <sup>th</sup> Percentile |           |
|                                                                                                    |                     | Exposure<br>(mg/kg/day)     | %<br>aPAD | Exposure<br>(mg/kg/day)     | %<br>aPAD | Exposure<br>(mg/kg/day)       | %<br>aPAD |
| Children 6-12 years old                                                                            |                     | 0.000018                    | 7.3       | 0.000042                    | 17        | 0.000082                      | 33        |
| Youth 13-19 years old                                                                              |                     | 0.000012                    | 4.8       | 0.000025                    | 10        | 0.000084                      | 33        |
| Adults 20-49 years old                                                                             |                     | 0.000016                    | 6.5       | 0.000032                    | 13        | 0.000077                      | 31        |
| Adults 50+ years old                                                                               |                     | 0.000018                    | 7.3       | 0.000035                    | 14        | 0.000093                      | 37        |
| Females 13-49 years old                                                                            |                     | 0.000016                    | 6.5       | 0.000033                    | 13        | 0.000076                      | 30        |

The results of the chronic dietary (food and drinking water) exposure analysis are reported in Table 5.4.6.2 below. The emamectin benzoate chronic dietary risk estimates for food and drinking water using the ornamental scenario for drinking water are below HED's level of concern for the general U.S. population and all population subgroups, at 7.5% of the cPAD for the general U.S. population and 16% of the cPAD for all infants (<1 year old), the most highly exposed population subgroup.

| Table 5.4.6.2. Summary of Dietary (Food and Drinking Water) Exposure and Risk for Emamectin Benzoate |                                    |           |                                 |           |
|------------------------------------------------------------------------------------------------------|------------------------------------|-----------|---------------------------------|-----------|
| Population Subgroup                                                                                  | Acute Dietary<br>(99.9 Percentile) |           | Chronic Dietary                 |           |
|                                                                                                      | Dietary Exposure<br>(mg/kg/day)    | % aPAD*   | Dietary Exposure<br>(mg/kg/day) | % cPAD*   |
| General U.S. Population                                                                              | 0.000091                           | 36        | 0.000006                        | 7.5       |
| All Infants (<1 year old)*                                                                           | 0.000138                           | 55        | <b>0.000012</b>                 | <b>16</b> |
| Children 1-2 years old*                                                                              | <b>0.000151</b>                    | <b>60</b> | 0.000011                        | 15        |
| Children 3-5 years old                                                                               | 0.000135                           | 54        | 0.000009                        | 12        |
| Children 6-12 years old                                                                              | 0.000082                           | 33        | 0.000006                        | 7.4       |
| Youth 13-19 years old                                                                                | 0.000084                           | 33        | 0.000004                        | 5.2       |
| Adults 20-49 years old                                                                               | 0.000077                           | 31        | 0.000005                        | 6.9       |
| Adults 50-99 years old                                                                               | 0.000093                           | 37        | 0.000006                        | 7.7       |
| Females 13-49 years old                                                                              | 0.000076                           | 30        | 0.000005                        | 6.8       |

\*The subpopulations with the highest risk estimates are bolded.

## 6.0 Residential (Non-Occupational) Exposure/Risk Characterization

There are no existing or proposed residential use sites; therefore, residential handler exposure and residential post-application exposure are not expected. Emamectin benzoate is registered for agricultural uses, as a tree injection use, and as a cockroach bait. Except for Optigard™ Cockroach Bait (EPA Reg. No. 100-1290), all registered emamectin benzoate end-use products are restricted use products (RUPs; restricted to use by professional certified operators [PCOs] only). Optigard™ Cockroach Bait is not a restricted use product but EPA has indicated that it is to be used only in commercial and industrial areas. Proclaim® Insecticide is an RUP which is proposed for use on cucurbits. Enfold™ Insecticide is an RUP which is proposed for use on outdoor-grown plants in commercial nursery production.

### 6.1 Residential Handler Exposure

Residential exposure is not expected from the registered/proposed products since they are agricultural uses rather than residential uses, restricted use products (restricted to use by certified applicators only), or limited to non-residential areas (commercial and industrial areas). Neither the proposed uses nor currently registered products would lead to residential handler exposure.

### 6.2 Post-Application Exposure

For reasons stated in Section 6.1 above, neither the proposed uses nor currently registered products would lead to residential post-application exposure. Residential exposures from commercial nursery production are expected to be negligible because the emamectin is expected to dissipate by the time the plant moves from a nursery, through a retail store, to the consumer.

### 6.3 Residential Bystander Post-application Inhalation Exposure

Based on the Agency's current practices, a quantitative post-application inhalation exposure assessment was not performed for emamectin benzoate at this time because the chemical has low vapor pressure ( $3.0 \times 10^{-8}$  mm Hg at 21 °C) and is applied at a low rate (0.015 lb ai/A). However, volatilization of pesticides may be a source of post-application inhalation exposure to individuals nearby pesticide applications. The Agency sought expert advice and input on issues related to volatilization of pesticides from its Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (SAP) in December 2009, and received the SAP's final report on March 2, 2010 (<http://www.epa.gov/scipoly/sap/meetings/2009/120109meeting.html>). The Agency is in the process of evaluating the SAP report and may, as appropriate, develop policies and procedures to identify the need for and, subsequently, the way to incorporate post-application inhalation exposure into the Agency's risk assessments. If new policies or procedures are developed, the Agency may revisit the need for a quantitative post-application inhalation exposure assessment for emamectin benzoate.



## 6.4 Spray Drift

Spray drift is always a potential source of exposure to residents nearby to spraying operations. This is particularly the case with aerial application, but, to a lesser extent, could also be a potential source of exposure from the ground application method employed for emamectin benzoate. The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation and other parties to develop the best spray drift management practices (see the Agency's Spray Drift website for more information at <http://www.epa.gov/opp00001/factsheets/spraydrift.htm>). On a chemical by chemical basis, the Agency is now requiring interim mitigation measures for aerial applications that must be placed on product labels/labeling. The Agency has completed its evaluation of the new database submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, and is developing a policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air, orchard airblast and ground hydraulic methods. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift with specific products with significant risks associated with drift.

Although a quantitative residential post-application inhalation exposure assessment was not performed as a result of pesticide drift from neighboring treated agricultural fields, an inhalation exposure assessment was performed for occupational flaggers. This exposure scenario is representative of a worse case inhalation (drift) exposure and may be considered protective of most outdoor agricultural and commercial post-application inhalation exposure scenarios.

## 7.0 Aggregate Exposure/Risk Characterization

In accordance with the FQPA, HED must consider and aggregate (add) pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. In an aggregate assessment, exposures from relevant sources are added together and compared to quantitative estimates of hazard (e.g., a NOAEL or PAD), or the risks themselves can be aggregated. When aggregating exposures and risks from various sources, HED considers both the route and duration of exposure.

### 7.1 Acute Aggregate Risk

Only food and drinking water are included in the acute aggregate assessment, as the Agency does not routinely assess any one-day residential exposures. Refer to section 5.4.3 for a detailed discussion of the acute dietary assessment.

### 7.2 Short-/Intermediate-Term Aggregate Risk

Short- and intermediate-term aggregate risk assessments were not conducted because existing and proposed uses are not expected to result in residential exposure.

### 7.3 Chronic Aggregate Risk

Chronic or long-term aggregate assessments include exposures that will exceed six months. Only food and drinking water are included in the chronic aggregate assessment, as the Agency does not routinely assess any long-term residential exposures. Refer to section 5.4.4 for a detailed discussion of the chronic dietary assessment.

### 7.4 Cancer Aggregate Risk

Emamectin benzoate is classified as “not likely to be carcinogenic to humans.”

## 8.0 Cumulative Exposure/Risk Characterization

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity (CMT), EPA has not made a common mechanism of toxicity finding as to emamectin benzoate and any other substances and emamectin benzoate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that emamectin benzoate has a common mechanism of toxicity with other substances.

OPP's *Guidance For Identifying Pesticide Chemicals and Other Substances that have a Common Mechanism of Toxicity* (USEPA, 1999) describes the weight of the evidence approach for determining whether or not a group of pesticides share a common mechanism of toxicity. This guidance defines mechanism of toxicity as the major steps leading to a toxic effect following interaction of a pesticide with biological targets. All steps leading to an effect do not need to be specifically understood. Rather, it is the identification of the crucial events following chemical interaction that are required in order to describe a mechanism of toxicity. For example, a mechanism of toxicity may be described by knowing the following: a chemical binds to a given biological target *in vitro*, and causes the receptor-related molecular response; *in vivo* it also leads to the molecular response and causes a number of intervening biological and morphological steps that result in an adverse effect. In this context a common mechanism of toxicity pertains to two or more pesticide chemicals or other substances that cause a common toxic effect to human health by the same, or essentially the same, sequence of major biochemical events. Hence, the underlying basis of the toxicity is the same, or essentially the same, for each chemical. In the case of the macrocyclic lactone pesticides (e.g., abamectin, emamectin, and avermectin), there is a wealth of data on the insecticidal mechanism of action for avermectin: its insecticidal actions are mediated by interaction with the glutamate-gated chloride channels and GABA<sub>A</sub> gated chloride channels. This is presumed to be the insecticidal mechanism of action of emamectin and abamectin as well. Mammals lack glutamate-gated chloride channels; the toxic actions of avermectin appear to be mediated via interaction with GABA<sub>A</sub> and possibly glycine gated chloride channels (Kamijima M, Casida JE, 2000). There is evidence that avermectin B<sub>1a</sub> binds to GABA<sub>A</sub> receptors and activates Cl<sup>-</sup> flux into neurons (Abalis et al., 1986; Huang and Casida,



1997). However, there is a paucity of data regarding the resultant alterations in cellular excitability of mammalian neurons and neural networks (i.e., changes in cellular excitability and altered network function as documented with pyrethroids), as well as *in vivo* measurements of altered excitability associated with adverse outcomes. Thus, while the downstream steps leading to toxicity via disruption of GABA<sub>A</sub> receptor function for avermectin can be postulated, experimental data supporting these actions are lacking. In addition, specific data demonstrating GABA<sub>A</sub> receptor interaction in mammalian preparations are lacking for abamectin and emamectin. Moreover, the specificity of such interaction on the adverse outcome would need to be shown experimentally. GABA<sub>A</sub> receptors have multiple binding sites which have been proposed to relate to adverse outcomes. For example, Dawson et al (2000) showed for a group of avermectin-like compounds that rank order for anticonvulsant activity did not parallel the rank order for affinity at the [<sup>3</sup>H]ivermectin site. The authors hypothesized that these findings may be related to differential affinity or efficacy at subtypes of the GABA<sub>A</sub> receptor. Other reports have indicated species differences in abamectin effects on GABA<sub>A</sub> receptor function in the mouse as compared to the rat (Soderlund et al., 1987).

In conclusion, although GABA<sub>A</sub> receptor mediated neurotoxicity is a strong hypothesis as a common mechanism endpoint for the macrocyclic lactone pesticides, data demonstrating the interactions of emamectin and abamectin with mammalian GABA<sub>A</sub> receptors are not available, and data in mammalian preparations linking alterations in GABA<sub>A</sub> receptor function to disruptions in neuronal excitability *in vitro* and *in vivo*, and ultimately adverse outcome, are also currently lacking for this class of compounds. In the absence of such data, the key biological steps leading to the adverse outcome (i.e., the mammalian mechanism of action) cannot be established and by extension a CMT cannot be established.

For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

## 9.0 Occupational Exposure/Risk Characterization

Based on application rate and label information, exposure from uses on cucurbits and ornamentals is expected to occur for short-and intermediate-term durations. However, intermediate-term exposure is less likely due to resistance management, and short-term scenarios are more realistic. Chronic exposure is not expected for the proposed use patterns.

### 9.1 Short-/Intermediate-Term Handler Risk

Occupational handler exposure to emamectin benzoate is expected for individuals involved in foliar applications to cucurbit vegetables (mixing, loading, flagging, and applying) and outdoor ornamentals (mixing, loading, and applying).



The toxicological effects for the dermal and inhalation routes were the same; however, since the levels of concern are not identical, the 1/ARI (aggregate risk index) approach was used. The risk estimates were calculated using the following formulas:

$$\text{MOE} = \text{NOAEL} / \text{Dose}$$

$$\text{ARI} = \text{MOE} / \text{LOC}$$

$$\text{Combined ARI} = 1 + ((1/\text{Dermal ARI}) + (1/\text{Inhalation ARI})).$$

All of the occupational handler exposure and risk estimate tables have been updated in this document since the two occupational and residential exposure (ORE) risk assessments previously conducted by Nancy Tsaur (DP390778, 12/07/2011; and DP393839, 03/01/2012). Summaries of the short- and intermediate-term risk estimates for occupational handlers from the uses on cucurbits and ornamentals are included in Appendix D, Tables D.1 through D.6. The maximum application rate for each exposure scenario is presented as the worst case scenario. The values in Tables D.1 through D.6 reflect current policies (i.e. changes to unit exposures, inhalation toxicity uncertainty factors, and body weights).

Based on the PPE required on the label, there are some risks of concern. Table 9.1 shows the PPE proposed on both labels (EPA Reg. No. 100-904 and EPA Reg. No. 100-RURR) along with mitigation recommendations based on short- and intermediate-term risk estimates. In order to achieve risk estimates that do not exceed HED's LOC (ARIs > 1.0), the recommendations based on intermediate-term exposure are more stringent. However, when considering resistance management, the short-term risk estimates are more representative of realistic exposure potential.

| Table 9.1. Occupational Exposure Mitigation Recommendations.                           |                                                                                                                                                                                  |                                                                                                                                                                  |                                                                                                                                                                  |
|----------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Proposed PPE on the Registered and Proposed Labels (EPA Reg. No. 100-904 and 100-RURR) |                                                                                                                                                                                  | Recommended Mitigation Based on Short-Term Risk Estimates                                                                                                        | Recommended Mitigation Based on Intermediate-Term Risk Estimates                                                                                                 |
| <b>Ground Application (except airblast sprayers)</b>                                   |                                                                                                                                                                                  |                                                                                                                                                                  |                                                                                                                                                                  |
| Mixers, Loaders, Other Handlers                                                        | Long-sleeved shirt and long pants.<br>Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber.<br>Shoes plus socks. | Option 1: Add a PF5 respirator for ornamentals. Add a PF10 respirator for cucurbit vegetables.<br><br>Option 2: Require engineering control of closed packaging. | Option 1: Add a PF5 respirator for ornamentals. Add a PF10 respirator for cucurbit vegetables.<br><br>Option 2: Require engineering control of closed packaging. |
| Applicators                                                                            | Long-sleeved shirt and long pants.<br>Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber.<br>Shoes plus socks. | Adequate.                                                                                                                                                        | Adequate.                                                                                                                                                        |
| <b>Handheld Application</b>                                                            |                                                                                                                                                                                  |                                                                                                                                                                  |                                                                                                                                                                  |
| Applicators, Mixers, Loaders, Other Handlers                                           | Not explicitly listed. May be assumed to be equivalent to "Ground Application."                                                                                                  | Adequate if assumed to be equivalent to "Ground Application."                                                                                                    | Add a PF5 respirator specifically for backpack sprayer application to ornamentals.                                                                               |
| <b>Airblast Application</b>                                                            |                                                                                                                                                                                  |                                                                                                                                                                  |                                                                                                                                                                  |



| Table 9.1. Occupational Exposure Mitigation Recommendations.                                                                                                                 |                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                               |                                                                                                                   |                                                                                                                   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|
| Mixers,<br>Loaders,<br>Other<br>Handlers                                                                                                                                     | Long-sleeved shirt and long pants.<br>Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber.<br>Shoes plus socks.                                                                                                                 |                                                                                                                                                                               | Option 1: Add a PF5 respirator for ornamentals.<br><br>Option 2: Require engineering control of closed packaging. | Option 1: Add a PF5 respirator for ornamentals.<br><br>Option 2: Require engineering control of closed packaging. |
| Applicators<br>Using OPEN<br>CAB                                                                                                                                             | Coveralls over long-sleeved shirt and long pants.<br>Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber.<br>Shoes plus socks.                                                                                                  |                                                                                                                                                                               | Option 1: Add a PF5 respirator.<br><br>Option 2: Prohibit OPEN CAB equipment.                                     | Prohibit OPEN CAB equipment.                                                                                      |
| Applicators<br>Using<br>ENCLOSED<br>CAB                                                                                                                                      | While inside the cockpit must wear:<br>Long-sleeved shirt and long pants.<br>Shoes plus socks.                                                                                                                                                                                                   | When entering or leaving the cockpit must also wear:<br>Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber. | Adequate.                                                                                                         | Adequate.                                                                                                         |
| Aerial Application                                                                                                                                                           |                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                               |                                                                                                                   |                                                                                                                   |
| Mixers,<br>Loaders,<br>Other<br>Handlers                                                                                                                                     | Coveralls over long-sleeved shirt and long pants.<br>Shoes plus socks.<br>Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber.<br>Dust/Mist-filtering respirator or a NIOSH-approved respirator with any N, R, P, or HE filter. |                                                                                                                                                                               | Adequate for ornamentals.<br><br>Require engineering control of closed packaging for cucurbit vegetables.         | Adequate for ornamentals.<br><br>Require engineering control of closed packaging for cucurbit vegetables.         |
| Applicators<br>(ENCLOSED<br>Cockpit)<br>NOTE: Once inside the cockpit, applicator must remove gloves and store them in a chemical-resistant container such as a plastic bag. | While inside the cockpit must wear:<br>Long-sleeved shirt and long pants.<br>Shoes plus socks.                                                                                                                                                                                                   | When entering or leaving the cockpit must also wear:<br>Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber. | Adequate.                                                                                                         | Adequate.                                                                                                         |
| Flaggers                                                                                                                                                                     | Long-sleeved shirt and long pants.<br>Shoes plus socks.<br>Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber.                                                                                                                 |                                                                                                                                                                               | Adequate.                                                                                                         | Adequate for ornamentals.<br><br>Add a PF5 respirator for cucurbit vegetables.                                    |

## 9.2 Short-/Intermediate-Term Post-Application Risk

Agricultural workers performing typical post-application activities with cucurbits and ornamentals such as scouting, irrigation, and harvesting are likely to receive exposure to emamectin benzoate residues based on the repeated use pattern to maintain control of pests.

### 9.2.1 Dermal Post-Application Risk

There is a potential for short- and intermediate-term occupational exposure during post-application activities. However, intermediate-term exposure is less likely due to resistance management, and short-term scenarios are more realistic. HED recommends utilizing the results from the short-term quantitative risk assessment because the intermediate-term results are highly conservative and unlikely due to the following reasons:

1. Due to resistance management of a Group 6 insecticide that has inherent risks of resistance development, the frequency of chemical application is expected to be limited to short-term use.
2. The intermediate-term day 0 assumptions are overly conservative and should be amortized if further refined (i.e., the likelihood of assuming day 0 residues every day for 90 days is not realistic).

The dermal post-application exposures associated with ornamentals and cucurbits are summarized in Appendix D, Table D.7. For short-term exposure, all scenarios resulted in MOEs greater than the short-term LOC of 300 (ranging from 520 to 11,000) on day 0 (12 hours after application) and, therefore, are not of concern to HED. For intermediate-term exposure, risk estimate MOEs are less than the intermediate-term LOC of 1000 and are of concern on day 0 (12 hours after application).

#### Restricted Entry Interval

Typically, under WPS for Agricultural Pesticides, active ingredients classified as acute Toxicity Category III or IV for acute dermal, eye irritation, and primary skin irritation are assigned a 12-hour REI.

### 9.2.2 Occupational Post-Application Inhalation Exposure

Based on the Agency's current practices, a quantitative occupational post-application inhalation exposure assessment was not performed for emamectin benzoate at this time because the chemical has low vapor pressure ( $3.0 \times 10^{-8}$  mm Hg at 21 °C) and is applied at a low rate (0.015 lb ai/A). However, there are multiple potential sources of post-application inhalation exposure to individuals performing post-application activities in previously treated fields. These potential sources include volatilization of pesticides and resuspension of dusts and/or particulates that contain pesticides. The Agency sought expert advice and input on issues related to volatilization of pesticides from its Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (SAP) in December 2009. The Agency received the SAP's final report on March 2, 2010



(<http://www.epa.gov/scipoly/SAP/meetings/2009/120109meeting.html>). The Agency is in the process of evaluating the SAP report as well as available post-application inhalation exposure data generated by the Agricultural Reentry Task Force. The Agency may, as appropriate, develop policies and procedures to identify the need for and, subsequently, the way to incorporate occupational post-application inhalation exposure into the Agency's risk assessments. If new policies or procedures are put into place, the Agency may revisit the need for a quantitative occupational post-application inhalation exposure assessment for emamectin benzoate.

Although a quantitative occupational post-application inhalation exposure assessment was not performed, an inhalation exposure assessment was performed for occupational/commercial handlers. Handler exposure resulting from application of pesticides outdoors is likely to result in higher exposure than post-application exposure. Therefore, it is expected that these handler inhalation exposure estimates would be protective of most occupational post-application inhalation exposure scenarios.

## 10.0 References

- Dodd, N., O'Rourke, K., and Phang, W., 7/31/08, DP Number D345943, *Emamectin Benzoate. Human Health Risk Assessment for Proposed Uses on Tree Nuts and Pistachios, and as an Injection Treatment for Ornamental/Nonbearing Trees.*
- Dodd, N., Phang, W., and Tsaur, N., 6/16/11, DP Number D385990, *Emamectin Benzoate. Human Health Assessment Scoping Document in Support of Registration Review.*
- Dodd, N., 8/6/12, DP Number D392510, *Emamectin Benzoate. Petition for the Establishment of a Permanent Tolerance on Vegetable, Cucurbit, Group 9. Summary of Analytical Chemistry and Residue Data.*
- Dodd, N., 12/19/12, DP Number 393838, *Emamectin Benzoate: Revised Acute and Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments for the Section 3 Registration Action on Cucurbits and Outdoor-Grown Plants in Commercial Nursery Production.*
- Tsaur, N., 12/7/11, DP Number D390788, *Emamectin Benzoate. Occupational Exposure Assessment for a Proposed Use on Outdoor-Grown Plants in Commercial Nursery Production.*
- Tsaur, N., 3/1/12, DP Number D393839, *Emamectin Benzoate. Occupational Exposure Assessment for a Proposed Use on Cucurbit Vegetables (Crop Group 9).*
- Dowen, T., 5/30/12, DP Number 402307, *Amended Drinking Water Assessment for the Proposed Use of Emamectin Benzoate on Outdoor Ornamentals and Group 9 Cucurbit Vegetables.*
- Alsadek, J., Ph.D., 8/21/12, DP Number 403689, *Percent Crop Treated for Emamectin Benzoate on Proposed New Uses for Cantaloupe, Cucumber, Squash, and Watermelons.*
- Alsadek, J., Ph.D., 5/29/12, DP Number 401786, *Emamectin Benzoate (122806) Screening Level Usage Analysis (SLUA).*

- Xue, M., 1/28/02, TXR#050315, *Emamectin. Conclusions of the 12/4/2001 Meeting of the HED Metabolism Assessment Review Committee (MARC) Meeting on Livestock Metabolism Studies.*



**Appendix A. Toxicology Profile and Executive Summaries****A.1 Toxicology Data Requirements**

The requirements (40 CFR 158.340) for food use for emamectin benzoate are in Table 1. Use of the new guideline numbers does not imply that the new (1998) guideline protocols were used.

| Study     |                                                     | Technical |           |
|-----------|-----------------------------------------------------|-----------|-----------|
|           |                                                     | Required  | Satisfied |
| 870.1100  | Acute Oral Toxicity .....                           | yes       | yes       |
| 870.1200  | Acute Dermal Toxicity .....                         | yes       | yes       |
| 870.1300  | Acute Inhalation Toxicity .....                     | yes       | yes       |
| 870.2400  | Acute Eye Irritation .....                          | yes       | yes       |
| 870.2500  | Acute Dermal Irritation .....                       | yes       | yes       |
| 870.2600  | Skin Sensitization .....                            | yes       | yes       |
| 870.3100  | 90-Day Oral Toxicity in Rodents .....               | yes       | yes       |
| 870.3150  | 90-Day Oral Toxicity in Nonrodents .....            | yes       | yes       |
| 870.3200  | 21/28-Day Dermal Toxicity .....                     | yes       | yes       |
| 870.3250  | 90-Day Dermal Toxicity .....                        | -         | -         |
| 870.3465  | 90-Day Inhalation Toxicity .....                    | yes       | no        |
| 870.3700a | Prenatal Developmental Toxicity (rodent) .....      | yes       | yes       |
| 870.3700b | Prenatal Developmental Toxicity (nonrodent) .....   | yes       | yes       |
| 870.3800  | Reproduction and Fertility Effects .....            | yes       | yes       |
| 870.4100a | Chronic Toxicity (rodent) .....                     | yes       | yes       |
| 870.4100b | Chronic Toxicity (nonrodent) .....                  | yes       | yes       |
| 870.4200a | Carcinogenicity (rat) .....                         | yes       | yes       |
| 870.4200b | Carcinogenicity (mouse) .....                       | yes       | yes       |
| 870.4300  | Combined Chronic Toxicity/Carcinogenicity .....     | yes       | yes       |
| 870.5100  | Mutagenicity—Bacterial Reverse Mutation Test .....  | yes       | yes       |
| 870.5300  | Mutagenicity—Mammalian Cell Gene Mutation Test ..   | yes       | yes       |
| 870.5385  | Mutagenicity—Structural Chromosomal Aberrations ... | yes       | yes       |
| 870.5xxx  | Mutagenicity—Other Genotoxic Effects .....          |           |           |
| 870.6200a | Acute Neurotoxicity Screening Battery (rat) .....   | yes       | yes       |
| 870.6200b | 90-Day Neurotoxicity Screening Battery (rat) .....  | yes       | yes       |
| 870.6300  | Developmental Neurotoxicity .....                   | CR        | -         |
| 870.7485  | Metabolism and Pharmacokinetics .....               | yes       | yes       |
| 870.7600  | Dermal Penetration .....                            | yes       | yes       |
| 870.7800  | Immunotoxicity .....                                | yes       | no        |

**A.2 Toxicity Profiles****Table A.2.1. Acute Toxicity Profile – Emamectin Benzoate Technical (EPA Reg. No. 100-902)**

| Guideline No. | Study Type                        | MRID     | Results                                       | Toxicity Category |
|---------------|-----------------------------------|----------|-----------------------------------------------|-------------------|
| 870.1100      | Acute oral - Rats                 | 42851519 | LD <sub>50</sub> for L-656,748-038 = 53 mg/kg | II                |
| 870.1200      | Acute dermal - Rabbits (EC)       | 43850111 | LD <sub>50</sub> > 2.0 g/kg                   | III               |
| 870.1300      | Acute inhalation - Rats           | 43868101 | 0.44 mg/L <LC <sub>50</sub> <2.12 mg/L        | III               |
| 870.2400      | Acute eye irritation - Rabbits    | 42743615 | Severe irritation                             | I                 |
| 870.2500      | Acute dermal irritation - Rabbits | 42743616 | No dermal irritation                          | IV                |
| 870.2600      | Skin sensitization - Guinea pigs  | 42743617 | Not a dermal sensitizer                       | -                 |

**Table A.2.2. Acute Toxicity Profile – Emamectin Benzoate Technical II (EPA Reg. No. 100-1270)**

| Guideline No. | Study Type                        | MRID     | Results                                       | Toxicity Category |
|---------------|-----------------------------------|----------|-----------------------------------------------|-------------------|
| 870.1100      | Acute oral - Rats                 | 47002104 | LD <sub>50</sub> for L-656,748-038 = 53 mg/kg | II                |
| 870.1200      | Acute dermal - Rabbits (EC)       | 47002106 | LD <sub>50</sub> > 2.0 g/kg                   | III               |
| 870.1300      | Acute inhalation - Rats           | 47002107 | LC <sub>50</sub> 0.10 mg/L                    | II                |
| 870.2400      | Acute eye irritation - Rabbits    | 47002108 | Severe irritation                             | III               |
| 870.2500      | Acute dermal irritation - Rabbits | 47002109 | No dermal irritation                          | IV                |
| 870.2600      | Skin sensitization - Guinea pigs  | 47002110 | Not a dermal sensitizer                       | Negative          |



**Table A. 2. 3. Repeated Dosing and Other Studies on Emamectin**

| Guideline No                                               | Study Type                                                                    | MRID No. (Year)/ Classification/Doses                                                                                                              | Results                                                                                                                                                                                                                                                                                                                                 |
|------------------------------------------------------------|-------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Acute dermal toxicity study (Not a LD <sub>50</sub> study) |                                                                               |                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                         |
|                                                            | Acute dermal tox.- rabbits<br>MK-0243 0.16 EC formulation                     | 42743611 (1991)<br>Acceptable<br>0, 0.5, 1.0, & 2.0 mg/kg<br>(2 groups: 4 hr exposure & 24 hr exposure) with collar on the test animals.           | 4 hr. exposure<br>NOAEL= 2.0 mg/kg/day (HDT)<br><br>24 hr. exposure<br>NOAEL = 0.5 mg/kg/day<br>LOAEL = 1.0 mg/kg/day one rabbit had neuron lesion occurred in cerebellar peduncle.                                                                                                                                                     |
|                                                            | Acute dermal tox. – rabbits (24 hrs exposure with collar on all test animals) | 43850111 (1995)<br>Acceptable<br>0, 10.4, 21.0, or 42.1 mg/kg MK-0244 0.16 EC                                                                      | NOAEL = 42.1 mg/kg. No treatment-related systemic toxicity was seen in any dosed animals. The acute dermal LD <sub>50</sub> > 2000 mg/kg for MK-0244                                                                                                                                                                                    |
| Subchronic toxicity studies                                |                                                                               |                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                         |
| 870.3100                                                   | 13-Wk oral-CD rats                                                            | 42794201 (1992)<br>Acceptable<br>0, 0.5, 2.5, and 12.5 mg/kg/day. 12.5 mg/kg/day was reduced to 8 mg/kg/day at wk 3 then to 5.0 mg/kg/day at wk 9. | Systemic Toxicity NOAEL=2.5 mg/kg/day;<br>Systemic Toxicity LOAEL=5 mg/kg/day based on moribundity, tremors, hindlimb splaying, urogenital staining, histological changes in brain and spinal cord, sciatic and optic nerves and skeletal muscles in males, emaciation, reduced body weight and reduced food consumption in both sexes. |
|                                                            | 13-Wk oral-CD-1 mice                                                          | 42743621 (1992)<br>Acceptable<br>0, 0.5, 4.5, & 15.0 mg/kg/day. An additional group received a time weighted dose 5.4 mg/kg/day                    | NOAEL = 5.4 mg/kg/day<br>LOAEL = 15.0 mg/kg/day based on mean body weight decrease and decreased in cumulative body weight gain.                                                                                                                                                                                                        |
| 870.3150                                                   | 90-Day oral – dogs (gavage)                                                   | 42743623 (1992)<br>Acceptable<br>0, 1.0, or 1.5 mg/kg/day for the first 2 wks then reduced to 0.25, 0.5, or 1.0 for the rest of the study.         | NOAEL = 0.25 mg/kg/day<br>LOAEL = 0.50 mg/kg/day based skeletal muscle atrophy and white matter multifocal degeneration in the brains of both sexes and white matter multifocal degeneration in the spinal cords of males.                                                                                                              |
|                                                            | 14-Wk oral-dogs (gavage)                                                      | 43868103 (1994)<br>Acceptable<br>0.5, 1.0, or 1.5 mg/kg/day for 2 wks for mid and high dose groups and for 3 wks                                   | NOAEL = 0.29 mg/kg/day<br>LOAEL = 0.58 mg/kg/day based on microscopic lesions in the brain (multifocal white matter degeneration), atrophy of skeletal muscle, and spinal cord lesions.                                                                                                                                                 |

**Table A. 2. 3. Repeated Dosing and Other Studies on Emamectin**

| Guideline No                    | Study Type                                                  | MRID No. (Year)/ Classification/Doses                                                                                                                                      | Results                                                                                                                                                                                                                                                                                             |
|---------------------------------|-------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                 |                                                             | for low dose, then they were reduced to 0.25, 0.5, or 2.0 mg/kg/day. The time weighted doses were 0.29, 0.58, or 0.1.08 mg/kg/day.                                         |                                                                                                                                                                                                                                                                                                     |
| 870.3200                        | 21-Day dermal tox-rabbits<br>MK-0244 0.16 EC formulation    | 42743625 (1992)<br>Acceptable<br>0, 50, 100, or 250 mg/kg/day (6 hrs/day)                                                                                                  | Systemic tox. NOAEL = 100 mg/kg/day<br>LOAEL = 250 mg/kg/day based on axonal degeneration of the sciatic nerve.<br><br>Application site irritation was seen in all treated rabbits.                                                                                                                 |
|                                 | 22-Day dermal tox. – rabbits<br>MK-0244 0.16 EC formulation | 44007902 (1996)<br>Acceptable<br>0, 250, 500, or 1000 mg/kg/day (6 hrs/day)                                                                                                | NOAEL = 1000 mg/kg/day (highest dose tested [HDT]). No systemic toxicity was seen in any dose groups.<br><i>Note: The test animals were collared to prevent oral ingestion of the test material.</i>                                                                                                |
| <b>Chronic toxicity studies</b> |                                                             |                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                     |
| 870.4100                        | 1-Year oral tox. – dogs (gavage)                            | 42763624 (1992)<br>Acceptable<br>0, 0.25, 0.5, 0.75, or 1.0 mg/kg/day (4 dogs/sex/dose)                                                                                    | NOAEL= 0.25 mg/kg/day<br>LOAEL=0.5 mg/kg/day based on axonal degeneration in the pons, medulla, and peripheral nerves (sciatic, sural, and tibial); whole body tremors; stiffness of the hind legs, spinal cord axonal degeneration, and muscle fiber degeneration.                                 |
|                                 | Chronic oral tox. – rats (dietary) (1 year)                 | 42868902 (1992)<br>Acceptable<br>0, 0.1, 1.0, 2.5 mg/kg (initially females received 5.0 mg/kg then reduced to 2.5 mg/kg at wk 18 due to excessive toxicity )               | <b>NOAEL=1.0 mg/kg/day</b><br><b>LOAEL=2.5 mg/kg/day</b> , based on increased incidence of neuronal degeneration in the brain and spinal cord, decreased rearing, and an increased incidence of animals with low arousal.                                                                           |
| 870.4200                        | Carcinogenicity study-mice (CD-1) (dietary)                 | 4386805 (1994)<br>Acceptable<br>0, 0.5, 2.5, or 12.5 mg/kg/day (The highest dose was reduced to 7.5 and 5.0 mg/kg/day for males at wk 9 and females at wk 3, respectively) | NOAEL=2.5 mg/kg/day.<br>LOAEL=5.0 mg/kg/day for males and 7.5 mg/kg/day for females based on increased mortality, decreased weight gain, tremors, sciatic nerve degeneration , and increased incidence of severity of infections.<br><br>No treatment-related increase in tumor incidence was seen. |



**Table A. 2. 3. Repeated Dosing and Other Studies on Emamectin**

| Guideline No                                  | Study Type                            | MRID No. (Year)/ Classification/Doses                                                                                                                                                                                                                | Results                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-----------------------------------------------|---------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                               | Combined Chronic/ Carcinogenicity-Rat | 43868104 (1994)<br>Acceptable<br>0, 0.25, 1.0, 2.5/5.0 mg/kg (Initially, high dose level was 5.0 mg/kg; it was reduced to 2.5 mg/kg on wk 6 for males and wk 10 for females due to tremors seen in another study at 5 mg/kg).                        | NOAEL=1.0 mg/kg/day<br>LOAEL=2.5/5.0 mg/kg/day <sup>1</sup> based on marked neural degeneration in the brain and spinal cord of both sexes, brain white matter degeneration in males, and on decreased body weight, body weight gain, and food efficiency in males.<br><br>No treatment-related increase in tumor incidence was seen.                                                                                                                           |
| <b>Developmental and Reproduction Studies</b> |                                       |                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 870.3700                                      | Developmental tox. -rat               | 42743632 (1992)<br>Acceptable<br>0, 2, 4, or 8 mg/kg/day<br><br>42743631 (range finding study)                                                                                                                                                       | <b>Maternal Toxicity NOAEL=2 mg/kg/day, Maternal Toxicity LOAEL=4 mg/kg/day</b> based on a significant trend towards decreased body weight gain during the dosing period.<br><br><b>Developmental Toxicity NOAEL=4 mg/kg/day, Developmental Toxicity LOAEL=8 mg/kg/day</b> based on altered growth and an increased incidence of supernumerary rib.                                                                                                             |
|                                               | Developmental tox. -rabbits           | 42743636 (1992)<br>Acceptable<br>0, 1.5, 3, or 6 mg/kg/day<br><br>42743635 (Range finding study)                                                                                                                                                     | <b>Maternal Tox. NOAEL= 3 mg/kg/day, Maternal Tox. LOAEL= 6 mg/kg/day</b> based on a significant trend towards decreased body weight gain during dosing period and increased clinical signs (mydriasis and decreased pupillary reaction).<br><br><b>Developmental Tox. NOAEL=6 mg/kg/day (HDT)</b>                                                                                                                                                              |
| 870.3800                                      | 2-Gen. reproduction study - rats      | 42851511 (1993)<br>Acceptable<br>0, 0.1, 0.6, or 3.8/1.8 mg/kg/day (F <sub>0</sub> & F <sub>1a</sub> females initially received 3.8 mg/kg, but it was reduced to 1.8 mg/kg/day on GD 0 following the second cohabitation of F <sub>0</sub> females). | Parental NOAEL = 0.6 mg/kg/day.<br>Parental LOAEL = 1.8 mg/kg/day based on decreased body weight gain and neuronal degeneration in the brain and spinal cord in both sexes and generations.<br><br>Reproductive NOAEL=0.6 mg/kg/day<br>Reproductive LOAEL=1.8 mg/kg/day based on decreased fecundity and fertility indices.<br><br>Offspring NOAEL = 0.6 mg/kg/day<br>Offspring LOAEL = 1.8 mg/kg/day based on tremors and hind limb extension in the offspring |

**Table A. 2. 3. Repeated Dosing and Other Studies on Emamectin**

| Guideline No                 | Study Type                                                                                                                                                | MRID No. (Year)/<br>Classification/Doses                                                 | Results                                                                                                                                                                                                                                         |
|------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                              |                                                                                                                                                           |                                                                                          | of both generations, neuronal degeneration in the brain and spinal cord.                                                                                                                                                                        |
| <b>Mutagenicity Studies</b>  |                                                                                                                                                           |                                                                                          |                                                                                                                                                                                                                                                 |
| 870.5100                     | 870.5100<br>Gene Mutation -<br><i>Salmonella</i><br>MK-0243 and L-<br>660,599; L-657,831;<br>L-695,638; L-<br>930,905<br>(photometabolites of<br>MK-0244) | 42743637<br>42851514<br>42851515<br>42851516<br>42851517                                 | Negative for the induction of reverse gene mutation.                                                                                                                                                                                            |
| 870.5300                     | Gene Mutation in<br>Cultured V-79<br>Chinese Hamster<br>Lung Cells<br>MK-0243                                                                             | 42743638                                                                                 | Negative for the induction of forward gene mutations in Chinese hamster lung fibroblast cells up to a severely cytotoxic nonactivated dose of 0.01 mM or a severely cytotoxic S9-activated dose of 0.04 mM.                                     |
| 870.5385                     | Structural<br>Chromosome<br>Aberration- <i>in vivo</i><br>mouse bone marrow<br>MK-0244                                                                    | 42851513                                                                                 | Negative for the induction of chromosome aberrations in the bone marrow cells of male CD-1 mice.                                                                                                                                                |
| <b>Neurotoxicity Studies</b> |                                                                                                                                                           |                                                                                          |                                                                                                                                                                                                                                                 |
| 870.6200                     | Acute neurotox.<br>study-rats (gavage)                                                                                                                    | 42743618 (1992)<br>Acceptable<br>0, 27.4, 54.8 or 82.2<br>mg/kg (range finding<br>study) | NOAEL was not established. LOAEL= 27.4 mg/kg/day (LDT); clinical signs (tremors, ataxia, loss of righting reflex, and reduced activities) and as histological lesions in the brain, spinal cord and sciatic nerve occurred at all doses tested. |
|                              | Acute neurotox.<br>study- rats<br>(gavage)                                                                                                                | 42743619 (1992)<br>Supplementary<br>0, 0.5, 2.5, 5.0, 10.0, or<br>25.0 mg/kg/day         | NOAEL = 5.0<br>LOAEL = 10 mg/kg/day based on tremors irritability. At 25 mg/kg, all rats had tremor and neuronal lesions (white matter degeneration of the brain, degeneration of the spinal cord and sciatic nerve.                            |
|                              | Subchronic<br>neurotox. -SD rats<br>(dietary) (14 day)                                                                                                    | 42743628 (1992)<br>Acceptable<br>0, 0.25, 1.0, or 5.0<br>mg/kg/day                       | NOAEL=1.0 mg/kg/day<br>LOAEL=5.0 mg/kg/day based on tremors, posture, rearing, excessive salivation, fur appearance, gait, strength, mobility and righting                                                                                      |



**Table A. 2. 3. Repeated Dosing and Other Studies on Emamectin**

| Guideline No | Study Type                                                                                                                                           | MRID No. (Year)/ Classification/Doses                                                              | Results                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|--------------|------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|              |                                                                                                                                                      |                                                                                                    | reflex. Neuronal vacuolation in brain and spinal cord; degeneration of nerve fiber in spinal cord and sciatic nerves. Skeletal muscle atrophy. Male rats appeared to be more affected than females.                                                                                                                                                                                                                                      |
|              | Comparative neurotox. – dogs (gavage) (14 days)                                                                                                      | 42743626 (1992)<br>Acceptable<br>2 dogs/sex/compound were given 1.5 mg/kg/day of testing compound. | The following effects were seen with different compounds:<br><br>Tremors<br><br>Mydriasis<br>MK-0243 <sup>a</sup> 2/4 0/4<br>L-682,901 0/4 0/4<br>L-653,648 0/4 4/4<br>L-653,649 2/4 3/4<br>L-655. 372 3/4 0/4<br>Histopathology findings were not seen in L-682, 901 and L-653,648 treated dogs. Neuronal degeneration of the brain, spinal cord, and sciatic nerves were seen in dogs treated with MK-0234, L-653, 649, and L-655,372. |
|              | 15-Day neurotox. – CD-1 mice (dietary)                                                                                                               | 42743629 (1992)<br>Acceptable<br>0, 0.6, 1.2, & 2.0 mg/kg/day                                      | NOAEL=2.0 mg/kg/day (HDT). No characteristic neuronal lesions in the brain, spinal cord or sciatic nerve in mice of high dose group.                                                                                                                                                                                                                                                                                                     |
|              | 15-Day neurotox. – CF-1 mice (dietary) (L-660,599: 4"-epi-(N-formyl-N-methyl)- amino4"-deoxy-avermectin B1                                           | 42851503 (1993)<br>Acceptable<br>0, 0.05, 0.075, 0.10, or 0.30 mg/kg/day                           | NOAEL=0.075 mg/kg/day<br>LOAEL=0.10 mg/kg/day based on tremors observed beginning on day 3, ptosis, hunched posture, decreases in body weight and food consumption as well as degeneration of the sciatic nerve. At 0.3 mg/kg, tremors were seen on day 2 and followed by hunched posture and ptosis, ataxia, and labored breathing.                                                                                                     |
|              | 15-Day neurotox. – CF-1 mice (dietary) (L695-638: 4"-deoxy-4"-epi-methylamino-avermectin B1a-delta-8,9-isomer); photoproduct of MK-0244 <sup>b</sup> | 42851504 (1993)<br>Acceptable<br>0, 0.05, 0.075, 0.10, & 0.30 mg/kg/day                            | NOAEL = 0.30 mg/kg/day (HDT)<br>No treatment-related effects were seen in any dose groups.                                                                                                                                                                                                                                                                                                                                               |
|              | 15-Day neurotox. –                                                                                                                                   | 42851505(1993)                                                                                     | NOAEL = 0.243 (HDT). The targeted dose was                                                                                                                                                                                                                                                                                                                                                                                               |

**Table A. 2. 3. Repeated Dosing and Other Studies on Emamectin**

| Guideline No | Study Type                                                                                                                  | MRID No. (Year)/ Classification/Doses                                                                                     | Results                                                                                                                                                                                                                                                                 |
|--------------|-----------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|              | CF-1 mice (dietary) (L695-638: 4"-deoxy-4"-epi-methylamino-avermectin B1a-delta-8,9-isomer); <b>photoproduct of MK-0244</b> | Acceptable<br>0, 0.05, 0.075, 0.10, & 0.30 mg/kg/day                                                                      | 0.30 mg/kg/day. No treatment-related effects were seen in any dose groups.<br><br>Female mice only to repeat the exposure dose levels of MRID 42851504 because female mice received 15% less than the targeted dose in that study.                                      |
|              | 15-Day neurotox.- CF-1 mice (dietary) (L-660,599; formyl methylamino plant metabolite of MK-0244 )                          | 42851506 (1993)<br>Acceptable<br>0, 0.10, 0.30, 0.90 mg/kg/day                                                            | LOAEL <0.1 mg/kg/day LDT) based on tremors, hunched posture and piloerection. However no treatment-related findings in histopathology were present.                                                                                                                     |
|              | 15-Day neurotox.- CF-1 mice (gavage) L-930,905; a complex mixture of polar MK-244 photodegradates)                          | 42851507 (1993)<br>Acceptable<br>0, 3, 6, 12, or 18 mg/kg/day                                                             | NOAEL = 18 mg/kg/day (HDT)<br>No treatment-related effects were found.                                                                                                                                                                                                  |
|              | 16-Day neurotox.- CF-1 mice (dietary) MK-0243                                                                               | 42743630 (1992)<br>Acceptable<br>0, 0.05, 0.10, 0.30, or 0.90 mg/kg/day                                                   | NOAEL = 0.1 mg/kg/day<br>LOAEL = 0.30 mg/kg/day based on tremors, decreased activity, and moribund sacrifice starting on day 2. However, no histopathology findings were present.                                                                                       |
|              | 15-Day neurotox.- CF-1 mice (dietary) Formyl amino derivative of MK-0244                                                    | 42868901 (1991)<br>Acceptable<br>0, 0.050, 0.075, 0.100, & 0.300 mg/kg/day                                                | NOAEL = 0.07 mg/kg/day<br>LOAEL = 0.23 mg/kg/day based on decreased body weight gain.                                                                                                                                                                                   |
| 870.6300     | Develop. Neurotox.- rats (SD) (gavage for maternal animals; no direct dosing for neonates) MK-0244                          | 42851508 (1993)<br>Acceptable<br>0, 0.1, 0.6, 3.6/2.5 mg/kg/day (3.6 mg/kg was reduced to 2.5 mg/kg between GD 17 and 20) | Maternal NOAEL=3.6/2.5 mg/kg/day (highest dose tested)<br>Develo. Neurotox. NOAEL=0.10 mg/kg/day<br>Develo. Neurotox. LOAEL = 0.60 mg/kg/day based on the dose-related decrease in open field motor activity in females at postnatal day 17.                            |
| 870.7485     | Metabolism -rats [ <sup>14</sup> C] 4"-deoxy-4"-epi-methylamino avermectin B1a benzoate, (MAB1a)                            | 42851523 & 42852524 (1993)<br>Acceptable                                                                                  | Radiolabeled MAB1a benzoate is rapidly absorbed, distributed and excreted following oral and i.v. administration. The feces was the major route of excretion in oral and i.v. groups, while <1% of the administered dose was recovered in the urine 7 days post dosing. |



**Table A. 2. 3. Repeated Dosing and Other Studies on Emamectin**

| Guideline No | Study Type                                                 | MRID No. (Year)/ Classification/Doses | Results                                                                                                                                                                                                                                                                                   |
|--------------|------------------------------------------------------------|---------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|              |                                                            |                                       | Tissue distribution and bioaccumulation appeared minimal. The metabolism of MAB1 a benzoate appears to involve primarily N-demethylation to AB1a. AB1a was the only metabolite detected in the feces while unmetabolized parent compound represented a large amount of the radioactivity. |
|              | Bioequivalence - Dog<br>MK-0243<br>solvate vs. monohydrate | 42743641(1992)<br>Supplemental        | The study demonstrated that MK-0243 benzoate MTBE solvate and MK-0243 benzoate monohydrate were bioequivalent in male dogs following oral administration as indicated by similar plasma levels for the two compounds.                                                                     |
|              | Bioequivalence-Dog<br>MK-0243 benzoate<br>vs. HCL salts    | 42743640 (1992)<br>Supplemental       | The study demonstrated that benzoate and HCl salts are bioequivalent after oral administration in male beagle dogs.                                                                                                                                                                       |
| 870.7600     | Dermal Absorption-Rhesus Monkey                            | 43850113 (1994)                       | Dermal Absorption was approximated at 1.79% of the administered dose.                                                                                                                                                                                                                     |
| 870.7800     | Immunotoxicity study                                       | Not available                         |                                                                                                                                                                                                                                                                                           |

## Appendix B. Physical/Chemical Properties

| Table B. Physicochemical Properties of Emamectin Benzoate Technical II.                        |                                                                                                                                                                                                                                                 |                                   |
|------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|
| Parameter                                                                                      | Value                                                                                                                                                                                                                                           | Reference                         |
| Molecular Weight                                                                               | emamectin benzoate B <sub>1a</sub> : 1008.26<br>emamectin benzoate B <sub>1b</sub> : 994.23                                                                                                                                                     | DP#335159, Indira Gairola, 8/7/07 |
| Melting point/range                                                                            | 141-146°C                                                                                                                                                                                                                                       | MRID #47002103                    |
| pH (at 25°C)                                                                                   | 6-7                                                                                                                                                                                                                                             |                                   |
| Density                                                                                        | 1.20 g/cm <sup>3</sup>                                                                                                                                                                                                                          |                                   |
| Water solubility (21°C)<br>(average of emamectin B <sub>1a</sub> + emamectin B <sub>1b</sub> ) | 105 mg/L at pure water<br>101 mg/L at pH 5.0<br>93 mg/L at pH 7.0<br><br>No peaks were observed at pH 9.0.                                                                                                                                      |                                   |
| Solvent solubility (25°C)                                                                      | Toluene 20.8 mg/mL<br>Cyclohexane 0.23 mg/mL<br>NMP 576 mg/mL<br><br>Acetone 140 g/L<br>Dichloromethane >500 g/L<br>Ethyl acetate 81 g/L<br>Hexane 77 g/L<br>Methanol 270 g/L<br>Octanol 48 g/L<br>Toluene 26 g/L                               |                                   |
| Vapor pressure (21°C)                                                                          | 3.0 x 10 <sup>-8</sup> torr or 3.0 x 10 <sup>-8</sup> mmHg                                                                                                                                                                                      |                                   |
| Dissociation constant, pKa                                                                     | 4.2 (benzoic acid)<br>7.6 (methyl-amino)                                                                                                                                                                                                        |                                   |
| Octanol/water partition coefficient                                                            | Shake Flask Method<br>Log P <sub>ow</sub> = 5.7 (emamectin B <sub>1a</sub> )<br>Log P <sub>ow</sub> = 5.2 (emamectin B <sub>1b</sub> )                                                                                                          |                                   |
| UV/visible absorption (molar absorption coefficients at the absorbance maxima)                 | Neutral: 37,367 l/mol•cm at 245 nm<br>22,584 l/mol•cm at 245 nm<br>Acidic: 36,841 l/mol•cm at 245 nm<br>22,131 l/mol•cm at 245 nm<br>Basic: 28,952 l/mol•cm at 245 nm<br><br>No further absorption maximum between 280 and 750 nm was observed. |                                   |
| Aerobic soil metabolism half-life                                                              | 90 <sup>th</sup> Percentile on the mean: 107.5 days;<br>Mean of all of the values (used in SCI-GROW): 79 days.                                                                                                                                  |                                   |



**Appendix C. Review of Human Research**

This risk assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide or other chemical. These studies, which comprise the Pesticide Handlers Exposure Database (PHED) and the Agricultural Handler Exposure Task Force (AHETF), have been determined to require a review of their ethical conduct, have received that review, and have been determined to be ethical.

**Studies reviewed for ethical conduct:**

No MRID - PHED Surrogate Exposure Guide, Agricultural Handler Exposure Task Force

**Studies reviewed by the Human Studies Review Board:**

None

## Appendix D. Occupational Exposure/Risk Summary Tables

| Table D.1. Short-Term Occupational Handler Non-Cancer Exposure and Risk Estimates for Emamectin Benzoate at Baseline PPE (single layer, no gloves, no respirator). |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|-----------------------------------|---------------------------------------|---------------------------------------|---------------------------------------------------|-------------------|------------------|-------------------|------------------|------------------------------|
| Exposure Scenario                                                                                                                                                  | Crop or Target            | Dermal Unit Exposure <sup>a</sup> | Inhalation Unit Exposure <sup>a</sup> | Maximum Application Rate <sup>b</sup> | Area Treated or Amount Handled Daily <sup>c</sup> | ST Dermal         |                  | ST Inhalation     |                  | Combined ST ARI <sup>h</sup> |
|                                                                                                                                                                    |                           |                                   |                                       |                                       |                                                   | Dose <sup>d</sup> | MOE <sup>e</sup> | Dose <sup>f</sup> | MOE <sup>g</sup> |                              |
|                                                                                                                                                                    |                           | µg/lb ai                          | lb ai/A                               | lb ai/A                               | mg/kg/day                                         | LOC = 300         | mg/kg/day        | LOC = 3000        | LOC = 1          |                              |
| Mixer/Loader at Baseline PPE (single layer, no gloves, no respirator)                                                                                              |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
| Mixing/Loading Dry Flowables for Groundboom Application                                                                                                            | Cucurbit Vegetables       | 227                               | 8.96                                  | 0.015                                 | 80                                                | 0.0000612         | 1,200            | 0.000135          | 560              | 0.18                         |
|                                                                                                                                                                    | Ornamentals (Nursery)     |                                   |                                       |                                       | 60                                                | 0.0000459         | 1,600            | 0.000101          | 740              | 0.24                         |
|                                                                                                                                                                    | Ornamentals (Field-Grown) |                                   |                                       |                                       | 40                                                | 0.0000306         | 2,500            | 0.0000673         | 1,100            | 0.35                         |
| Mixing/Loading Dry Flowables for Aerial Application                                                                                                                | Cucurbit Vegetables       |                                   |                                       |                                       | 350                                               | 0.000268          | 280              | 0.000588          | 130              | 0.041                        |
|                                                                                                                                                                    | Ornamentals (Nursery)     |                                   |                                       |                                       | 60                                                | 0.0000459         | 1,600            | 0.000101          | 740              | 0.24                         |
| Mixing/Loading Dry Flowables for Airblast Application                                                                                                              | Ornamentals (Nursery)     |                                   |                                       |                                       | 20                                                | 0.0000153         | 4,900            | 0.0000336         | 2,200            | 0.70                         |
| Applicator at Baseline PPE <sup>*</sup> (single layer, no gloves, no respirator)                                                                                   |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
| Applying Sprays via Groundboom Equipment                                                                                                                           | Cucurbit Vegetables       | 78.6                              | 0.34                                  | 0.015                                 | 80                                                | 0.0000212         | 3,500            | 0.00000510        | 15,000           | 3.5                          |
|                                                                                                                                                                    | Ornamentals (Nursery)     |                                   |                                       |                                       | 60                                                | 0.0000159         | 4,700            | 0.00000383        | 20,000           | 4.7                          |
|                                                                                                                                                                    | Ornamentals (Field-Grown) |                                   |                                       |                                       | 40                                                | 0.0000106         | 7,100            | 0.00000255        | 29,000           | 6.9                          |
| Applying Sprays via Aerial Equipment <sup>*</sup>                                                                                                                  | Cucurbit Vegetables       | 5                                 | 0.068                                 |                                       | 350                                               | 0.00000592        | 13,000           | 0.00000446        | 17,000           | 5.0                          |
|                                                                                                                                                                    | Ornamentals (Nursery)     | 5                                 | 0.068                                 |                                       | 60                                                | 0.00000101        | 74,000           | 0.000000765       | 98,000           | 29                           |
| Applying Sprays via Airblast Equipment                                                                                                                             | Ornamentals (Nursery)     | 1770                              | 4.71                                  |                                       | 20                                                | 0.000119          | 630              | 0.0000176         | 4,300            | 0.85                         |
| Flagger at Baseline PPE (single layer, no gloves, no respirator)                                                                                                   |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
| Flagging for Aerial Application                                                                                                                                    | Cucurbit Vegetables       | 11                                | 0.35                                  | 0.015                                 | 350                                               | 0.000013          | 5,800            | 0.0000230         | 3,300            | 1.0                          |
|                                                                                                                                                                    | Ornamentals (Nursery)     |                                   |                                       |                                       | 60                                                | 0.00000223        | 34,000           | 0.000000394       | 19,000           | 6.0                          |
| Mixer/Loader/Applicator at Baseline PPE (single layer, no gloves, no respirator)                                                                                   |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
| M/L/A for Backpack Sprayer                                                                                                                                         | Ornamentals (Nursery)     | 13200                             | 140                                   | 0.00030 lb ai/gal                     | 40 gallons                                        | 0.0000356         | 2,100            | 0.0000210         | 3,600            | 1.0                          |
|                                                                                                                                                                    |                           | 8260                              | 2.58                                  |                                       |                                                   | 0.0000223         | 3,400            | 0.000000388       | 190,000          | 9.6                          |
| M/L/A for Manually-Pressurized Handwand                                                                                                                            | Ornamentals (Nursery)     | 100000                            | 30                                    |                                       | 0.00027                                           | 280               | 0.00000450       | 17,000            | 0.8              |                              |
| M/L/A for Mechanically-Pressurized Handgun                                                                                                                         | Ornamentals (Nursery)     | 1300                              | 3.9                                   |                                       | 1000 gallons                                      | 0.0000878         | 850              | 0.0000146         | 5,100            | 1.1                          |

a Based on the "Occupational Pesticide Handler Unit Exposure Surrogate Reference Table" (March 2012). \*Baseline aircraft = engineering controls.

b Based on registered and proposed label (Reg. No. 100-904 Enfold™ Insecticide for cucurbit vegetables and 100-RURR Proclaim® Insecticide for ornamentals).

c Based on Exposure Science Advisory Council Policy No. 9.1.

d Dermal Dose = Dermal Unit Exposure (µg/lb ai) × Conversion Factor (0.001 mg/µg) × Application Rate (lb ai/acre or gal) × Area Treated or Amount Handled Daily (A or gal/day) × Dermal Absorption Factor (%) ÷ Body Weight (80 kg). Dermal absorption factor = 1.8%.

e Dermal MOE = Dermal NOAEL (mg/kg/day) ÷ Dermal Dose (mg/kg/day). ST Dermal NOAEL = 0.075 mg/kg/day. Dermal level of concern = 300.

f Inhalation Dose = Inhalation Unit Exposure (µg/lb ai) × Conversion Factor (0.001 mg/µg) × Application Rate (lb ai/acre or gal) × Area Treated or Amount Handled Daily (A or gal/day) ÷ BW (80 kg). No inhalation absorption factor (inhalation is equivalent to oral).

g Inhalation MOE = Inhalation NOAEL (mg/kg/day) ÷ Inhalation Dose (mg/kg/day). ST Inhalation NOAEL = 0.075 mg/kg/day. Inhalation level of concern = 3000.

h ST ARI = MOE / LOC. Combined ST ARI = 1 ÷ ((1/Dermal ARI) + (1/Inhalation ARI)). ARI level of concern = 1.



Table D.2. Short-Term Occupational Handler Non-Cancer Exposure and Risk Estimates for Emamectin Benzoate with PPE Required on Labels.<sup>a</sup>

| Exposure Scenario                                                                           | Crop or Target            | Dermal Unit Exposure <sup>b</sup> | Inhalation Unit Exposure <sup>b</sup> | Maximum Application Rate <sup>c</sup> | Area Treated or Amount Handled Daily <sup>d</sup> | ST Dermal         |                  | ST Inhalation     |                  | Combined ST ARI <sup>i</sup> |
|---------------------------------------------------------------------------------------------|---------------------------|-----------------------------------|---------------------------------------|---------------------------------------|---------------------------------------------------|-------------------|------------------|-------------------|------------------|------------------------------|
|                                                                                             |                           |                                   |                                       |                                       |                                                   | Dose <sup>e</sup> | MOE <sup>f</sup> | Dose <sup>g</sup> | MOE <sup>h</sup> |                              |
|                                                                                             |                           | µg/lb ai                          | lb ai/A                               | lb ai/A                               | acres                                             | mg/kg/day         | LOC = 300        | mg/kg/day         | LOC = 3000       |                              |
| Ground Equipment Mixer/Loader with Label-Required PPE (single layer, gloves, no respirator) |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
| Mixing/Loading Dry Flowables for Groundboom Application                                     | Cucurbit Vegetables       | 51.6                              | 8.96                                  | 0.015                                 | 80                                                | 0.0000139         | 5,400            | 0.0000135         | 560              | 0.18                         |
|                                                                                             | Ornamentals (Nursery)     |                                   |                                       |                                       | 60                                                | 0.0000104         | 7,200            | 0.000101          | 740              | 0.24                         |
|                                                                                             | Ornamentals (Field-Grown) |                                   |                                       |                                       | 40                                                | 0.00000698        | 11,000           | 0.0000673         | 1,100            | 0.36                         |
| Mixing/Loading Dry Flowables for Airblast Application                                       | Ornamentals (Nursery)     |                                   |                                       |                                       | 20                                                | 0.00000349        | 21,000           | 0.0000336         | 2,200            | 0.73                         |
| Aerial Equipment Mixer/Loader with Label-Required PPE (double layer, gloves, PF5)           |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
| Mixing/Loading Dry Flowables for Aerial Application                                         | Cucurbit Vegetables       | 41.2                              | 1.792                                 | 0.015                                 | 350                                               | 0.0000486         | 1,500            | 0.000118          | 640              | 0.20                         |
|                                                                                             | Ornamentals (Nursery)     |                                   |                                       |                                       | 60                                                | 0.00000835        | 9,000            | 0.0000201         | 3,700            | 1.2                          |
| Applicator with Label-Required PPE (single layer, gloves, no respirator)                    |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
| Applying Sprays via Groundboom Equipment                                                    | Cucurbit Vegetables       | 16.1                              | 0.34                                  | 0.015                                 | 80                                                | 0.00000434        | 17,000           | 0.00000510        | 15,000           | 4.6                          |
|                                                                                             | Ornamentals (Nursery)     |                                   |                                       |                                       | 60                                                | 0.00000326        | 23,000           | 0.00000383        | 20,000           | 6.1                          |
|                                                                                             | Ornamentals (Field-Grown) |                                   |                                       |                                       | 40                                                | 0.00000217        | 35,000           | 0.00000255        | 29,000           | 8.9                          |
| Applying Sprays via Aerial Equipment*                                                       | Cucurbit Vegetables       | 5                                 | 0.068                                 |                                       | 350                                               | 0.00000592        | 74,000           | 0.00000446        | 17,000           | 5.0                          |
|                                                                                             | Ornamentals (Nursery)     |                                   |                                       | 60                                    | 0.00000101                                        | 13,000            | 0.000000765      | 98,000            | 29               |                              |
| Applicator with Label-Required PPE (double layer, gloves, no respirator)                    |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
| Applying Sprays via Open Cab Airblast Equipment                                             | Ornamentals (Nursery)     | 1480                              | 4.71                                  | 0.015                                 | 20                                                | 0.0000999         | 750              | 0.0000176         | 4,300            | 0.91                         |
| Flagger at Baseline PPE (single layer, gloves, no respirator)                               |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
| Flagging for Aerial Application                                                             | Cucurbit Vegetables       | 12                                | 0.35                                  | 0.015                                 | 350                                               | 0.0000142         | 5,300            | 0.0000230         | 3,300            | 1.0                          |
|                                                                                             | Ornamentals (Nursery)     |                                   |                                       |                                       | 60                                                | 0.00000243        | 31,000           | 0.00000394        | 19,000           | 6.0                          |
| Handheld Equipment with Label-Required PPE (single layer, gloves, no respirator)            |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
| M/L/A for Backpack Sprayer                                                                  | Ornamentals (Nursery)     | 13200                             | 140                                   | 0.00030 lb ai/gal                     | 40 gallons                                        | 0.0000302         | 2,500            | 0.0000210         | 3,600            | 1.0                          |
|                                                                                             |                           | 8260                              | 2.58                                  |                                       |                                                   | 0.0000223         | 3,400            | 0.000000388       | 190,000          | 9.6                          |
| M/ L/A for Manually-Pressurized Handwand                                                    | Ornamentals (Nursery)     | 430                               | 30                                    |                                       | 0.00000116                                        | 65,000            | 0.00000450       | 17,000            | 5.5              |                              |
| M/L/A for Mechanically-Pressurized Handgun                                                  | Ornamentals (Nursery)     | 390                               | 3.9                                   |                                       | 1000 gallons                                      | 0.0000263         | 2,900            | 0.0000146         | 5,100            | 1.4                          |

a PPE = Personal Protective Equipment. PPE based on registered and proposed labels. See Table D.7.

b Based on the "Occupational Pesticide Handler Unit Exposure Surrogate Reference Table" (March 2012). \*Baseline aircraft = engineering controls.

c Based on registered and proposed labels (Reg. No. 100-904 Enfold™ Insecticide for cucurbit vegetables and 100-RURR Proclaim® Insecticide for ornamentals).

d Based on Exposure Science Advisory Council Policy No. 9.1.

e Dermal Dose = Dermal Unit Exposure (µg/lb ai) × Conversion Factor (0.001 mg/µg) × Application Rate (lb ai/acre or gal) × Area Treated or Amount Handled Daily (A or gal/day) × Dermal Absorption Factor (%) ÷ Body Weight (80 kg). Dermal absorption factor = 1.8%.

f Dermal MOE = Dermal NOAEL (mg/kg/day) ÷ Dermal Dose (mg/kg/day). ST Dermal NOAEL = 0.075 mg/kg/day. Dermal level of concern = 300.

g Inhalation Dose = Inhalation Unit Exposure (µg/lb ai) × Conversion Factor (0.001 mg/µg) × Application Rate (lb ai/acre or gal) × Area Treated or Amount Handled Daily (A or gal/day) ÷ BW (80 kg). No inhalation absorption factor (inhalation is equivalent to oral).

h Inhalation MOE = Inhalation NOAEL (mg/kg/day) ÷ Inhalation Dose (mg/kg/day). ST Inhalation NOAEL = 0.075 mg/kg/day. Inhalation level of concern = 3000.

i ST ARI = MOE / LOC. Combined ST ARI = 1 ÷ ((1/Dermal ARI) + (1/Inhalation ARI)). ARI level of concern = 1.

Table D.3. Short-Term Occupational Handler Non-Cancer Exposure and Risk Estimates for Emamectin Benzoate with PPE Required on Labels and Additional Mitigation.<sup>a</sup>

| Exposure Scenario                                                                                                             | Crop or Target            | Dermal Unit Exposure <sup>b</sup> | Inhalation Unit Exposure <sup>b</sup> | Maximum Application Rate <sup>c</sup> | Area Treated or Amount Handled Daily <sup>d</sup> | ST Dermal         |                  | ST Inhalation     |                  | Combined ST ARI <sup>i</sup> |
|-------------------------------------------------------------------------------------------------------------------------------|---------------------------|-----------------------------------|---------------------------------------|---------------------------------------|---------------------------------------------------|-------------------|------------------|-------------------|------------------|------------------------------|
|                                                                                                                               |                           |                                   |                                       |                                       |                                                   | Dose <sup>e</sup> | MOE <sup>f</sup> | Dose <sup>g</sup> | MOE <sup>h</sup> |                              |
|                                                                                                                               |                           | µg/lb ai                          | lb ai/A                               | acres                                 | mg/kg/day                                         | LOC = 300         | mg/kg/day        | LOC = 3000        | LOC = 1          |                              |
| GROUND EQUIPMENT M/L OPTION 1: Mixer/Loader with Label-Required PPE + PF5 Respirator (single layer, gloves, PF5 respirator)   |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
| Mixing/Loading Dry Flowables for Groundboom Application                                                                       | Ornamentals (Nursery)     | 51.6                              | 1.792                                 | 0.015                                 | 60                                                | 0.0000104         | 7,200            | 0.0000201         | 3,700            | 1.2                          |
|                                                                                                                               | Ornamentals (Field-Grown) |                                   |                                       |                                       | 40                                                | 0.00000698        | 11,000           | 0.0000135         | 5,600            | 1.8                          |
| Mixing/Loading Dry Flowables for Airblast Application                                                                         | Ornamentals (Nursery)     |                                   |                                       |                                       | 20                                                | 0.00000349        | 21,000           | 0.00000673        | 11,000           | 3.5                          |
| GROUND EQUIPMENT M/L OPTION 1: Mixer/Loader with Label-Required PPE + PF10 Respirator (single layer, gloves, PF10 respirator) |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
| Mixing/Loading Dry Flowables for Groundboom Application                                                                       | Cucurbit Vegetables       | 51.6                              | 0.896                                 | 0.015                                 | 80                                                | 0.0000139         | 5,400            | 0.0000135         | 5,600            | 1.7                          |
| GROUND EQUIPMENT M/L OPTION 2: Mixer/Loader with EC (engineering control of closed packaging)                                 |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
| Mixing/Loading Dry Flowables for Groundboom Application                                                                       | Cucurbit Vegetables       | 9.8                               | 0.24                                  | 0.015                                 | 80                                                | 0.00000266        | 28,000           | 0.00000360        | 21,000           | 6.5                          |
|                                                                                                                               | Ornamentals (Nursery)     |                                   |                                       |                                       | 60                                                | 0.00000198        | 38,000           | 0.00000270        | 28,000           | 8.7                          |
|                                                                                                                               | Ornamentals (Field-Grown) |                                   |                                       |                                       | 40                                                | 0.00000132        | 57,000           | 0.00000180        | 42,000           | 13                           |
| Mixing/Loading Dry Flowables for Airblast Application                                                                         | Ornamentals (Nursery)     |                                   |                                       |                                       | 20                                                | 0.000000662       | 110,000          | 0.000000900       | 83,000           | 26                           |
| AERIAL EQUIPMENT M/L ONLY OPTION: Mixer/Loader with EC (engineering control of closed packaging)                              |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
| Mixing/Loading Dry Flowables for Aerial Application                                                                           | Cucurbit Vegetables       | 9.8                               | 0.24                                  | 0.015                                 | 350                                               | 0.0000116         | 6,500            | 0.0000158         | 4,700            | 1.5                          |
| AIRBLAST APP OPTION 1: Applicator with Label-Required PPE + PF5 Respirator (double layer, gloves, PF5 respirator)             |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
| Applying Sprays via Open Cab Airblast Equipment                                                                               | Ornamentals (Nursery)     | 1480                              | 0.942                                 | 0.015                                 | 20                                                | 0.0000999         | 750              | 0.00000354        | 21,000           | 1.8                          |
| AIRBLAST APP OPTION 2: Applicator with EC (engineering control of closed cab equipment)                                       |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
| Applying Sprays via Closed Cab Airblast Equipment                                                                             | Ornamentals (Nursery)     | 14.6                              | 0.068                                 | 0.015                                 | 20                                                | 0.000000986       | 76,000           | 0.000000255       | 290,000          | 70                           |

a PPE = Personal Protective Equipment. PPE based on registered and proposed labels. See Table d.7.

b Based on the "Occupational Pesticide Handler Unit Exposure Surrogate Reference Table" (March 2012).

c Based on registered and proposed labels (Reg. No. 100-904 Enfold™ Insecticide for cucurbit vegetables and 100-RURR Proclaim® Insecticide for ornamentals).

d Based on Exposure Science Advisory Council Policy No. 9.1.

e Dermal Dose = Dermal Unit Exposure ( $\mu\text{g/lb ai}$ )  $\times$  Conversion Factor (0.001 mg/ $\mu\text{g}$ )  $\times$  Application Rate (lb ai/acre or gal)  $\times$  Area Treated or Amount Handled Daily (A or gal/day)  $\times$  Dermal Absorption Factor (%)  $\div$  Body Weight (80 kg). Dermal absorption factor = 1.8%.

f Dermal MOE = Dermal NOAEL (mg/kg/day)  $\div$  Dermal Dose (mg/kg/day). ST Dermal NOAEL = 0.075 mg/kg/day. Dermal level of concern = 300.

g Inhalation Dose = Inhalation Unit Exposure ( $\mu\text{g/lb ai}$ )  $\times$  Conversion Factor (0.001 mg/ $\mu\text{g}$ )  $\times$  Application Rate (lb ai/acre or gal)  $\times$  Area Treated or Amount Handled Daily (A or gal/day)  $\div$  BW (80 kg). No inhalation absorption factor (inhalation is equivalent to oral).

h Inhalation MOE = Inhalation NOAEL (mg/kg/day)  $\div$  Inhalation Dose (mg/kg/day). ST Inhalation NOAEL = 0.075 mg/kg/day. Inhalation level of concern = 3000.

i ST ARI = MOE / LOC. Combined ST ARI =  $1 + ((1/\text{Dermal ARI}) + (1/\text{Inhalation ARI}))$ . ARI level of concern = 1.



| Table D.4. Intermediate-Term Occupational Handler Non-Cancer Exposure and Risk Estimates for Emamectin Benzoate at Baseline PPE (single layer, no gloves, no respirator). |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|-----------------------------------|---------------------------------------|---------------------------------------|---------------------------------------------------|-------------------|------------------|-------------------|------------------|------------------------------|
| Exposure Scenario                                                                                                                                                         | Crop or Target            | Dermal Unit Exposure <sup>a</sup> | Inhalation Unit Exposure <sup>a</sup> | Maximum Application Rate <sup>b</sup> | Area Treated or Amount Handled Daily <sup>c</sup> | IT Dermal         |                  | IT Inhalation     |                  | Combined IT ARI <sup>h</sup> |
|                                                                                                                                                                           |                           | µg/lb ai                          | lb ai/A                               | lb ai/A                               | acres                                             | Dose <sup>d</sup> | MOE <sup>e</sup> | Dose <sup>f</sup> | MOE <sup>g</sup> |                              |
|                                                                                                                                                                           |                           |                                   |                                       |                                       |                                                   | mg/kg/day         | LOC = 1000       | mg/kg/day         | LOC = 3000       |                              |
| Mixer/Loader at Baseline PPE (single layer, no gloves, no respirator)                                                                                                     |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
| Mixing/Loading Dry Flowables for Groundboom Application                                                                                                                   | Cucurbit Vegetables       | 227                               | 8.96                                  | 0.015                                 | 80                                                | 0.0000612         | 1,200            | 0.000135          | 560              | 0.16                         |
|                                                                                                                                                                           | Ornamentals (Nursery)     |                                   |                                       |                                       | 60                                                | 0.0000459         | 1,600            | 0.000101          | 740              | 0.21                         |
|                                                                                                                                                                           | Ornamentals (Field-Grown) |                                   |                                       |                                       | 40                                                | 0.0000306         | 2,500            | 0.0000673         | 1,100            | 0.32                         |
| Mixing/Loading Dry Flowables for Aerial Application                                                                                                                       | Cucurbit Vegetables       |                                   |                                       |                                       | 350                                               | 0.000268          | 280              | 0.000588          | 130              | 0.038                        |
|                                                                                                                                                                           | Ornamentals (Nursery)     |                                   |                                       |                                       | 60                                                | 0.0000459         | 1,600            | 0.000101          | 740              | 0.21                         |
| Mixing/Loading Dry Flowables for Airblast Application                                                                                                                     | Ornamentals (Nursery)     |                                   |                                       |                                       | 20                                                | 0.0000153         | 4,900            | 0.0000336         | 2,200            | 0.64                         |
| Applicator at Baseline PPE <sup>h</sup> (single layer, no gloves, no respirator)                                                                                          |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
| Applying Sprays via Groundboom Equipment                                                                                                                                  | Cucurbit Vegetables       | 78.6                              | 0.34                                  | 0.015                                 | 80                                                | 0.0000212         | 3,500            | 0.00000510        | 15,000           | 2.1                          |
|                                                                                                                                                                           | Ornamentals (Nursery)     |                                   |                                       |                                       | 60                                                | 0.0000159         | 4,700            | 0.00000383        | 20,000           | 2.8                          |
|                                                                                                                                                                           | Ornamentals (Field-Grown) |                                   |                                       |                                       | 40                                                | 0.0000106         | 7,100            | 0.00000255        | 29,000           | 4.1                          |
| Applying Sprays via Aerial Equipment <sup>a</sup>                                                                                                                         | Cucurbit Vegetables       | 5                                 | 0.068                                 |                                       | 350                                               | 0.00000592        | 74,000           | 0.00000446        | 17,000           | 3.9                          |
|                                                                                                                                                                           | Ornamentals (Nursery)     | 5                                 | 0.068                                 |                                       | 60                                                | 0.00000101        | 13,000           | 0.000000765       | 98,000           | 23                           |
| Applying Sprays via Airblast Equipment                                                                                                                                    | Ornamentals (Nursery)     | 1770                              | 4.71                                  |                                       | 20                                                | 0.000119          | 630              | 0.0000176         | 4,300            | 0.44                         |
| Flagger at Baseline PPE (single layer, no gloves, no respirator)                                                                                                          |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
| Flagging for Aerial Application                                                                                                                                           | Cucurbit Vegetables       | 11                                | 0.35                                  | 0.015                                 | 350                                               | 0.000013          | 5,800            | 0.0000230         | 3,300            | 0.92                         |
|                                                                                                                                                                           | Ornamentals (Nursery)     |                                   |                                       |                                       | 60                                                | 0.00000223        | 34,000           | 0.000000394       | 19,000           | 5.3                          |
| Mixer/Loader/Applicator at Baseline PPE (single layer, no gloves, no respirator)                                                                                          |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
| M/L/A for Backpack Sprayer                                                                                                                                                | Ornamentals (Nursery)     | 13200                             | 140                                   | 0.00030 lb ai/gal                     | 40 gallons                                        | 0.0000356         | 2,100            | 0.0000210         | 3,600            | 0.76                         |
|                                                                                                                                                                           |                           | 8260                              | 2.58                                  |                                       |                                                   | 0.0000223         | 3,400            | 0.000000388       | 190,000          | 3.2                          |
| M/L/A for Manually-Pressurized Handwand                                                                                                                                   | Ornamentals (Nursery)     | 100000                            | 30                                    |                                       |                                                   | 0.00027           | 280              | 0.00000450        | 17,000           | 0.27                         |
| M/L/A for Mechanically-Pressurized Handgun                                                                                                                                | Ornamentals (Nursery)     | 1300                              | 3.9                                   |                                       | 1000 gallons                                      | 0.0000878         | 850              | 0.0000146         | 5,100            | 0.57                         |

a Based on the "Occupational Pesticide Handler Unit Exposure Surrogate Reference Table" (March 2012). Baseline aircraft = engineering controls.

b Based on registered and proposed label (Reg. No. 100-904 Enfold™ Insecticide for cucurbit vegetables and 100-RURR Proclaim® Insecticide for ornamentals).

c Based on Exposure Science Advisory Council Policy No. 9.1.

d Dermal Dose = Dermal Unit Exposure (µg/lb ai) × Conversion Factor (0.001 mg/µg) × Application Rate (lb ai/acre or gal) × Area Treated or Amount Handled Daily (A or gal/day) × Dermal Absorption Factor (%) ÷ Body Weight (80 kg). Dermal absorption factor = 1.8%.

e Dermal MOE = Dermal NOAEL (mg/kg/day) ÷ Dermal Dose (mg/kg/day). IT Dermal NOAEL = 0.075 mg/kg/day. Dermal level of concern = 1000.

f Inhalation Dose = Inhalation Unit Exposure (µg/lb ai) × Conversion Factor (0.001 mg/µg) × Application Rate (lb ai/acre or gal) × Area Treated or Amount Handled Daily (A or gal/day) ÷ BW (80 kg). No inhalation absorption factor (inhalation is equivalent to oral).

g Inhalation MOE = Inhalation NOAEL (mg/kg/day) ÷ Inhalation Dose (mg/kg/day). IT Inhalation NOAEL = 0.075 mg/kg/day. Inhalation level of concern = 3000.

h IT ARI = MOE / LOC. Combined ARI = 1 ÷ ((1/Dermal ARI) + (1/Inhalation ARI)). ARI level of concern = 1.

**Table D.5. Intermediate-Term Occupational Handler Non-Cancer Exposure and Risk Estimates for Emamectin Benzoate with PPE Required on Labels.<sup>a</sup>**

| Exposure Scenario                                                                           | Crop or Target            | Dermal Unit Exposure <sup>b</sup> | Inhalation Unit Exposure <sup>b</sup> | Maximum Application Rate <sup>c</sup> | Area Treated or Amount Handled Daily <sup>d</sup> | IT Dermal         |                  | IT Inhalation     |                  | Combined IT ARI <sup>i</sup> |
|---------------------------------------------------------------------------------------------|---------------------------|-----------------------------------|---------------------------------------|---------------------------------------|---------------------------------------------------|-------------------|------------------|-------------------|------------------|------------------------------|
|                                                                                             |                           |                                   |                                       |                                       |                                                   | Dose <sup>e</sup> | MOE <sup>f</sup> | Dose <sup>g</sup> | MOE <sup>h</sup> |                              |
|                                                                                             |                           | µg/lb ai                          | lb ai/A                               |                                       | acres                                             | mg/kg/day         | LOC = 1000       | mg/kg/day         | LOC = 3000       |                              |
| Ground Equipment Mixer/Loader with Label-Required PPE (single layer, gloves, no respirator) |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
| Mixing/Loading Dry Flowables for Groundboom Application                                     | Cucurbit Vegetables       | 51.6                              | 8.96                                  | 0.015                                 | 80                                                | 0.0000139         | 5,400            | 0.000135          | 560              | 0.18                         |
|                                                                                             | Ornamentals (Nursery)     |                                   |                                       |                                       | 60                                                | 0.0000104         | 7,200            | 0.000101          | 740              | 0.24                         |
|                                                                                             | Ornamentals (Field-Grown) |                                   |                                       |                                       | 40                                                | 0.00000698        | 11,000           | 0.0000673         | 1,100            | 0.35                         |
| Mixing/Loading Dry Flowables for Airblast Application                                       | Ornamentals (Nursery)     |                                   |                                       |                                       | 20                                                | 0.00000349        | 21,000           | 0.0000336         | 2,200            | 0.71                         |
| Aerial Equipment Mixer/Loader with Label-Required PPE (double layer, gloves, PF5)           |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
| Mixing/Loading Dry Flowables for Aerial Application                                         | Cucurbit Vegetables       | 41.2                              | 1.792                                 | 0.015                                 | 350                                               | 0.0000486         | 1,500            | 0.000118          | 640              | 0.19                         |
|                                                                                             | Ornamentals (Nursery)     |                                   |                                       |                                       | 60                                                | 0.00000835        | 9,000            | 0.0000201         | 3,700            | 1.1                          |
| Applicator with Label-Required PPE (single layer, gloves, no respirator)                    |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
| Applying Sprays via Groundboom Equipment                                                    | Cucurbit Vegetables       | 16.1                              | 0.34                                  | 0.015                                 | 80                                                | 0.00000434        | 17,000           | 0.00000510        | 15,000           | 3.9                          |
|                                                                                             | Ornamentals (Nursery)     |                                   |                                       |                                       | 60                                                | 0.00000326        | 23,000           | 0.00000383        | 20,000           | 5.2                          |
|                                                                                             | Ornamentals (Field-Grown) |                                   |                                       |                                       | 40                                                | 0.00000217        | 35,000           | 0.00000255        | 29,000           | 7.6                          |
| Applying Sprays via Aerial Equipment*                                                       | Cucurbit Vegetables       | 5                                 | 0.068                                 |                                       | 350                                               | 0.00000592        | 13,000           | 0.00000446        | 17,000           | 3.9                          |
|                                                                                             | Ornamentals (Nursery)     |                                   |                                       | 60                                    | 0.00000101                                        | 74,000            | 0.000000765      | 98,000            | 23               |                              |
| Applicator with Label-Required PPE (double layer, gloves, no respirator)                    |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
| Applying Sprays via Open Cab Airblast Equipment                                             | Ornamentals (Nursery)     | 1480                              | 4.71                                  | 0.015                                 | 20                                                | 0.0000999         | 750              | 0.0000176         | 4,300            | 0.49                         |
| Flagger at Label-Required PPE (single layer, gloves, no respirator)                         |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
| Flagging for Aerial Application                                                             | Cucurbit Vegetables       | 12                                | 0.35                                  | 0.015                                 | 350                                               | 0.0000142         | 5,300            | 0.0000230         | 3,300            | 0.91                         |
|                                                                                             | Ornamentals (Nursery)     |                                   |                                       |                                       | 60                                                | 0.00000243        | 31,000           | 0.00000394        | 19,000           | 5.3                          |
| Handheld Equipment with Label-Required PPE (single layer, gloves, no respirator)            |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
| M/L/A for Backpack Sprayer                                                                  | Ornamentals (Nursery)     | 11200                             | 140                                   | 0.00030 lb ai/gal                     | 40 gallons                                        | 0.0000302         | 2,500            | 0.0000210         | 3,600            | 0.81                         |
|                                                                                             |                           | 8260                              | 2.58                                  |                                       |                                                   | 0.0000223         | 3,400            | 0.00000388        | 190,000          | 3.2                          |
| M/L/A for Manually-Pressurized Handwand                                                     | Ornamentals (Nursery)     | 430                               | 30                                    |                                       |                                                   | 0.00000116        | 65,000           | 0.00000450        | 17,000           | 5.2                          |
| M/L/A for Mechanically-Pressurized Handgun                                                  | Ornamentals (Nursery)     | 390                               | 3.9                                   |                                       | 1000 gallons                                      | 0.0000263         | 2,900            | 0.0000146         | 5,100            | 1.1                          |

a PPE = Personal Protective Equipment. PPE based on registered and proposed labels. See Table D.7.

b Based on the "Occupational Pesticide Handler Unit Exposure Surrogate Reference Table" (March 2012). \*Baseline aircraft = engineering controls.

c Based on registered and proposed labels (Reg. No. 100-904 Enfold™ Insecticide for cucurbit vegetables and 100-RURR Proclaim® Insecticide for ornamentals).

d Based on Exposure Science Advisory Council Policy No. 9.1.

e Dermal Dose = Dermal Unit Exposure (µg/lb ai) × Conversion Factor (0.001 mg/µg) × Application Rate (lb ai/acre or gal) × Area Treated or Amount Handled Daily (A or gal/day) × Dermal Absorption Factor (%) ÷ Body Weight (80 kg). Dermal absorption factor = 1.8%.

f Dermal MOE = Dermal NOAEL (mg/kg/day) ÷ Dermal Dose (mg/kg/day). ST Dermal NOAEL = 0.075 mg/kg/day. Dermal level of concern = 300.

g Inhalation Dose = Inhalation Unit Exposure (µg/lb ai) × Conversion Factor (0.001 mg/µg) × Application Rate (lb ai/acre or gal) × Area Treated or Amount Handled Daily (A or gal/day) ÷ BW (80 kg). No inhalation absorption factor (inhalation is equivalent to oral).

h Inhalation MOE = Inhalation NOAEL (mg/kg/day) ÷ Inhalation Dose (mg/kg/day). ST Inhalation NOAEL = 0.075 mg/kg/day. Inhalation level of concern = 3000.

i IT ARI = MOE / LOC. Combined ST ARI = 1 + ((1/Dermal ARI) + (1/Inhalation ARI)). ARI level of concern = 1.



| Table D.6. Intermediate-Term Occupational Handler Non-Cancer Exposure and Risk Estimates for Emamectin Benzoate with PPE Required on Labels and Recommended Mitigation. <sup>a</sup> |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|-----------------------------------|---------------------------------------|---------------------------------------|---------------------------------------------------|-------------------|------------------|-------------------|------------------|------------------------------|
| Exposure Scenario                                                                                                                                                                    | Crop or Target            | Dermal Unit Exposure <sup>b</sup> | Inhalation Unit Exposure <sup>b</sup> | Maximum Application Rate <sup>c</sup> | Area Treated or Amount Handled Daily <sup>d</sup> | IT Dermal         |                  | IT Inhalation     |                  | Combined IT ARI <sup>i</sup> |
|                                                                                                                                                                                      |                           |                                   |                                       |                                       |                                                   | Dose <sup>e</sup> | MOE <sup>f</sup> | Dose <sup>g</sup> | MOE <sup>h</sup> |                              |
|                                                                                                                                                                                      |                           | µg/lb ai                          | lb ai/A                               | acres                                 | mg/kg/day                                         | LOC = 1000        | mg/kg/day        | LOC = 3000        | LOC = 1          |                              |
| GROUND EQUIPMENT M/L OPTION 1: Mixer/Loader with Label-Required PPE + PF5 Respirator (single layer, gloves, PF5 respirator)                                                          |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
| Mixing/Loading Dry Flowables for Groundboom Application                                                                                                                              | Ornamentals (Nursery)     | 51.6                              | 1.792                                 | 0.015                                 | 60                                                | 0.0000104         | 7,200            | 0.0000201         | 3,700            | 1.1                          |
|                                                                                                                                                                                      | Ornamentals (Field-Grown) |                                   |                                       |                                       | 40                                                | 0.00000698        | 11,000           | 0.0000135         | 5,600            | 1.6                          |
| Mixing/Loading Dry Flowables for Airblast Application                                                                                                                                | Ornamentals (Nursery)     |                                   |                                       |                                       | 20                                                | 0.00000349        | 21,000           | 0.00000673        | 11,000           | 3.1                          |
| GROUND EQUIPMENT M/L OPTION 1: Mixer/Loader with Label-Required PPE + PF10 Respirator (single layer, gloves, PF10 respirator)                                                        |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
| Mixing/Loading Dry Flowables for Groundboom Application                                                                                                                              | Cucurbit Vegetables       | 51.6                              | 0.896                                 | 0.015                                 | 80                                                | 0.0000139         | 5,400            | 0.0000135         | 5,600            | 1.4                          |
| GROUND EQUIPMENT M/L OPTION 2: Mixer/Loader with EC (engineering control of closed packaging)                                                                                        |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
| Mixing/Loading Dry Flowables for Groundboom Application                                                                                                                              | Cucurbit Vegetables       | 9.8                               | 0.24                                  | 0.015                                 | 80                                                | 0.00000266        | 28,000           | 0.00000360        | 21,000           | 5.6                          |
|                                                                                                                                                                                      | Ornamentals (Nursery)     |                                   |                                       |                                       | 60                                                | 0.00000198        | 38,000           | 0.00000270        | 28,000           | 7.5                          |
|                                                                                                                                                                                      | Ornamentals (Field-Grown) |                                   |                                       |                                       | 40                                                | 0.00000132        | 57,000           | 0.00000180        | 42,000           | 11                           |
| Mixing/Loading Dry Flowables for Airblast Application                                                                                                                                | Ornamentals (Nursery)     |                                   |                                       |                                       | 20                                                | 0.000000662       | 110,000          | 0.000000900       | 83,000           | 22                           |
| AERIAL EQUIPMENT M/L ONLY OPTION: Mixer/Loader with EC (engineering control of closed packaging)                                                                                     |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
| Mixing/Loading Dry Flowables for Aerial Application                                                                                                                                  | Cucurbit Vegetables       | 9.8                               | 0.24                                  | 0.015                                 | 350                                               | 0.0000116         | 6,500            | 0.0000158         | 4,700            | 1.3                          |
| AIRBLAST APP ONLY OPTION: Applicator with EC (engineering control of closed cab equipment)                                                                                           |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
| Applying Sprays via Closed Cab Airblast Equipment                                                                                                                                    | Ornamentals (Nursery)     | 14.6                              | 0.068                                 | 0.015                                 | 20                                                | 0.000000986       | 76,000           | 0.000000255       | 290,000          | 43                           |
| FLAGGER at Label-Required PPE + PF5 Respirator (single layer, gloves, PF5 respirator)                                                                                                |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
| Flagging for Aerial Application                                                                                                                                                      | Cucurbit Vegetables       | 12                                | 0.07                                  | 0.015                                 | 350                                               | 0.0000142         | 5,300            | 0.00000460        | 16,000           | 2.7                          |
| HANDHELD EQUIPMENT with Label-Required PPE + PF5 Respirator (single layer, gloves, PF5 respirator)                                                                                   |                           |                                   |                                       |                                       |                                                   |                   |                  |                   |                  |                              |
| M/L/A for Backpack Sprayer                                                                                                                                                           | Ornamentals (Nursery)     | 11200                             | 28                                    | 0.00030 lb ai/gal                     | 40 gallons                                        | 0.0000302         | 2,500            | 0.00000420        | 18,000           | 1.8                          |

a PPE = Personal Protective Equipment. PPE based on registered and proposed labels. See Table.

b Based on the "Occupational Pesticide Handler Unit Exposure Surrogate Reference Table" (March 2012).

c Based on registered and proposed labels (Reg. No. 100-904 Enfold™ Insecticide for cucurbit vegetables and 100-RURR Proclaim® Insecticide for ornamentals).

d Based on Exposure Science Advisory Council Policy No. 9.1.

e Dermal Dose = Dermal Unit Exposure (µg/lb ai) × Conversion Factor (0.001 mg/µg) × Application Rate (lb ai/acre or gal) × Area Treated or Amount Handled Daily (A or gal/day) × Dermal Absorption Factor (%) ÷ Body Weight (80 kg). Dermal absorption factor = 1.8%.

f Dermal MOE = Dermal NOAEL (mg/kg/day) ÷ Dermal Dose (mg/kg/day). ST Dermal NOAEL = 0.075 mg/kg/day. Dermal level of concern = 300.

g Inhalation Dose = Inhalation Unit Exposure (µg/lb ai) × Conversion Factor (0.001 mg/µg) × Application Rate (lb ai/acre or gal) × Area Treated or Amount Handled Daily (A or gal/day) ÷ BW (80 kg). No inhalation absorption factor (inhalation is equivalent to oral).

h Inhalation MOE = Inhalation NOAEL (mg/kg/day) ÷ Inhalation Dose (mg/kg/day). ST Inhalation NOAEL = 0.075 mg/kg/day. Inhalation level of concern = 3000.

i IT ARI = MOE / LOC. Combined ST ARI = 1 ÷ ((1/Dermal ARI) + (1/Inhalation ARI)). ARI level of concern = 1.

**Table D.7. Short- and Intermediate-Term Post-Application Exposures and Risk Estimates for Emamectin Benzoate for Commercially Grown Outdoor Ornamentals (Field- and Container-Grown)<sup>a</sup> and Cucurbit Vegetables (Crop Group 9).**

| Activity                                                                                                                                                          | Transfer Coefficient | Days After Treatment | DFR <sup>b</sup>          | Daily Dermal Dose <sup>c</sup>   | Dermal MOE <sup>d</sup>       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|---------------------------|----------------------------------|-------------------------------|
|                                                                                                                                                                   |                      |                      | $\mu\text{g}/\text{cm}^2$ | $\text{mg}/\text{kg}/\text{day}$ | ST LOC = 300<br>IT LOC = 1000 |
| irrigation (hand set)<br>[ornamentals and CG9]                                                                                                                    | 1,900                | 0<br>(12 hours)      | 0.0421                    | 0.000144                         | 520                           |
|                                                                                                                                                                   |                      | 1                    | 0.0378                    | 0.000129                         | 580                           |
|                                                                                                                                                                   |                      | 2                    | 0.0341                    | 0.000116                         | 640                           |
|                                                                                                                                                                   |                      | 3                    | 0.0307                    | 0.000105                         | 720                           |
|                                                                                                                                                                   |                      | 4                    | 0.0276                    | 0.000094                         | 790                           |
|                                                                                                                                                                   |                      | 5                    | 0.0248                    | 0.000085                         | 880                           |
|                                                                                                                                                                   |                      | 6                    | 0.0223                    | 0.000076                         | 980                           |
|                                                                                                                                                                   |                      | 7                    | 0.0201                    | 0.000069                         | 1,100                         |
| harvesting<br>[ornamentals]                                                                                                                                       | 1,400                | 0<br>(12 hours)      | 0.0421                    | 0.000106                         | 710                           |
|                                                                                                                                                                   |                      | 1                    | 0.0378                    | 0.000095                         | 790                           |
|                                                                                                                                                                   |                      | 2                    | 0.0341                    | 0.000086                         | 870                           |
|                                                                                                                                                                   |                      | 3                    | 0.0307                    | 0.000077                         | 970                           |
|                                                                                                                                                                   |                      | 4                    | 0.0276                    | 0.000070                         | 1,100                         |
| scouting, shaping<br>[ornamentals]                                                                                                                                | 580                  | 0<br>(12 hours)      | 0.0421                    | 0.000044                         | 1,700                         |
| hand harvesting, turning, training,<br>mechanical harvesting<br>[CG9]                                                                                             | 550                  | 0<br>(12 hours)      | 0.0421                    | 0.000042                         | 1,800                         |
| hand harvesting, hand pruning, scouting,<br>container moving, hand weeding,<br>transplanting, grafting, propagating,<br>pinching, tying/training<br>[ornamentals] | 230                  | 0<br>(12 hours)      | 0.0421                    | 0.000017                         | 4,300                         |
| transplanting<br>[CG9]                                                                                                                                            | 230                  | 0<br>(12 hours)      | 0.0421                    | 0.000017                         | 4,300                         |
| hand weeding, grading/tagging<br>[ornamentals]                                                                                                                    | 100                  | 0<br>(12 hours)      | 0.0421                    | 0.0000076                        | 9,900                         |
| scouting, hand weeding, hand pruning,<br>thinning fruit<br>[CG9]                                                                                                  | 90                   | 0<br>(12 hours)      | 0.0421                    | 0.0000068                        | 11,000                        |

a These values in this table have been updated since the ORE (N. Tsaur, DP390788, 12/07/2011) to reflect policy changes in body weight and day 0 residue assumptions.

b  $\text{DFR } (\mu\text{g}/\text{cm}^2) = \text{application rate } (0.015 \text{ lb ai/acre}) \times \text{fraction of application rate dislodgeable on day 0 } (25\%) \times (1 - \text{fraction of residue that dissipates daily } 10\%)^t \times 4.54\text{E}8 \mu\text{g/lb} \times 2.47\text{E}-8 \text{ acre}/\text{cm}^2$ .

c Short-/Intermediate-Term Daily Dermal Dose =  $[\text{DFR } (\mu\text{g}/\text{cm}^2) \times \text{Transfer Coefficient} \times 0.001 \text{ mg}/\mu\text{g} \times 8 \text{ hrs}/\text{day} \times \text{dermal absorption } 1.8\%] \div \text{body weight } (80 \text{ kg adult})$ .

d Short-/Intermediate-Term MOE =  $\text{NOAEL } (\text{mg}/\text{kg}/\text{day}) / \text{Daily Dermal Dose } (\text{mg}/\text{kg}/\text{day})$ . ST/IT NOAEL = 0.075 mg/kg/day. Short-term level of concern = 300. Intermediate-term level of concern = 1000.



## Appendix E. International Tolerances

## Emamectin Benzoate (122806; 08/06/2012)

| Summary of US and International Tolerances and Maximum Residue Limits                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                |                     |                                                                                                                                                                                           |                                                 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|---------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| Residue Definition:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                |                     |                                                                                                                                                                                           |                                                 |
| US                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Canada                                         | Mexico <sup>2</sup> | Codex <sup>3</sup>                                                                                                                                                                        |                                                 |
| 40 CFR 180.505:<br>Plant: Combined residues of emamectin (a mixture of a minimum of 90% 4'-epi-methylamino-4'-deoxyavermectin B <sub>1a</sub> and maximum of 10% 4'-epi-methylamino-4'-deoxyavermectin B <sub>1b</sub> ) and its metabolites 8,9-isomer of the B <sub>1a</sub> and B <sub>1b</sub> component of the parent (8,9-ZMA), or 4'-deoxy-4'-epi-amino-avermectin B <sub>1a</sub> and 4'-deoxy-4'-epi-amino-avermectin B <sub>1b</sub> ; 4'-deoxy-4'-epi-amino avermectin B <sub>1a</sub> (AB <sub>1a</sub> ); 4'-deoxy-4'-epi-(N-formyl-N-methyl)amino-avermectin (MFB <sub>1a</sub> ); and 4'-deoxy-4'-epi-(N-formyl)amino-avermectin B <sub>1a</sub> (FAB <sub>1a</sub> ).<br>Livestock: Combined residues of emamectin (MAB <sub>1a</sub> + MAB <sub>1b</sub> isomers) and the associated 8,9-Z isomers (8,9-ZB <sub>1a</sub> + 8,9-ZB <sub>1b</sub> ). | None                                           |                     | Plants: emamectin B1a benzoate, expressed as emamectin (free base).<br>animal commodities: emamectin B1a benzoate, expressed as emamectin (free base).<br>The residue is not fat-soluble. |                                                 |
| Commodity <sup>1</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Tolerance (ppm) /Maximum Residue Limit (mg/kg) |                     |                                                                                                                                                                                           |                                                 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | US                                             | Canada              | Mexico <sup>2</sup>                                                                                                                                                                       | Codex <sup>3</sup>                              |
| Vegetable, cucurbit, group 9                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 0.02                                           |                     |                                                                                                                                                                                           | 0.007 fruiting vegetables, cucurbits (proposed) |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                |                     |                                                                                                                                                                                           |                                                 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                |                     |                                                                                                                                                                                           |                                                 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                |                     |                                                                                                                                                                                           |                                                 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                |                     |                                                                                                                                                                                           |                                                 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                |                     |                                                                                                                                                                                           |                                                 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                |                     |                                                                                                                                                                                           |                                                 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                |                     |                                                                                                                                                                                           |                                                 |
| Completed: M. Negussie; 08/20/2012                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                |                     |                                                                                                                                                                                           |                                                 |

<sup>1</sup> Includes only commodities of interest for this action. Tolerance values should be the HED recommendations and not those proposed by the applicant.

<sup>2</sup> Mexico adopts US tolerances and/or Codex MRLs for its export purposes.

<sup>3</sup> \* = absent at the limit of quantitation; Po = postharvest treatment, such as treatment of stored grains. PoP = processed postharvest treated commodity, such as processing of treated stored wheat. (fat) = to be measured on the fat portion of the sample. MRLs indicated as proposed have not been finalized by the CCPR and the CAC.

**Appendix F. Toxicology Literature References**

- Dawson GR, Wafford KA, Smith A, Marshall GR, Bayley PJ, Schaeffer JM, Meinke PT, McKernan RM. (2000) Anticonvulsant and adverse effects of avermectin analogs in mice are mediated through the gamma-aminobutyric acid (A) receptor. *J. Pharmacol. Exp. Ther.* 295: 1051-1060.
- Huang J, Casida JE. (1997) Avermectin B<sub>1a</sub> binds to high- and low-affinity sites with dual effects on the gamma-aminobutyric acid-gated chloride channel of cultured cerebellar granule neurons. *J. Pharmacol. Exp. Ther.* 281: 261-266.
- Kerb R (2006) Implication of genetic polymorphism in drug transporters for pharmacotherapy. *Cancer Lett.* 234: 4-33.
- Kerr DI and Ong J. (1986) Gama-aminobutyric acid-dependent motility induced by avermectin B<sub>1a</sub> in the isolated intestine of the guinea pigs. *Neurosci. Lett.* 65: 7-10.
- Lankas GR, Cartwright ME, and Umbenhauer D (1997) P-Glycoprotein deficiency in a subpopulation of CF-1 mice enhances avermectin-induced neurotoxicity. *Toxicol. and Appl. Pharmacol.* 143: 357-365.
- Marzolini C, Paus E, Buclin T, and Kim RB (2004) Polymorphism I human MDR1 (P-glycoprotein): Recent advances and clinical relevance. *Clin. Pharmacol. and Ther.* 75: 13-33.
- Meister B. (2007) Neurotransmitters in key neurons of the hypothalamus that regulate feeding behavior and body weight. *Physiol. Behav.* 92: 263-271.
- Nguyen L, Rigo JM, Rocher V, Belachew S, Malgrange B, Rogister B, Leprince P, Moonen G. (2001) Neurotransmitters as early signals for central nervous system development. *Cell Tissue Res.* 305: 187-202.
- Niles, AT and Keppler, D (2007) The apical conjugate efflux pump ABCC2 (MRP2). *Pflugers Arch-Eur J Physiol* (2007) 453: 643-659.
- Pong SS, DeHaven R, Wang CC. (1982) A comparative study of avermectin B<sub>1a</sub> and other modulators of the gamma-aminobutyric receptor- chloride ion channel complex. *J. Neurosci.* 2: 966-971.
- Represa A, Ben-Ari Y. (2005) Trophic actions of GABA on neuronal development. *Trends Neurosci.* 28: 278-283.
- Habashi, SL (2006) Dubin-Johnson Syndrome. [http://www.emedicine.com/med/topic\\_588.htm](http://www.emedicine.com/med/topic_588.htm)



Wang CC, Pong SS. (1982) Actions of avermectin B<sub>1a</sub> on GABA nerves. Prog. Clin. Biol. Res. 97: 373-395.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



OFFICE OF CHEMICAL SAFETY AND  
POLLUTION PREVENTION

supercedes 8/29/2012 version

MEMORANDUM

Date: 19-DEC-2012

SUBJECT: **Emamectin Benzoate:** Revised Acute and Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessments for the Section 3 Registration Action on Cucurbits and Outdoor-Grown Plants in Commercial Nursery Production

PC Code: 122806

Decision No.: 452138

Petition No.: 1E7904

Risk Assessment Type: NA

TXR No.: NA

DP Barcode: D393838

Registration Nos.: 100-904, 100-RURR

Regulatory Action: Section 3 Registration

Case No.: NA

CAS No.: 155569-91-8 (emamectin benzoate)  
119791-41-2 (emamectin)

MRID No.: NA

40 CFR: §180.505

FROM: Nancy Dodd, Chemist *Nancy Dodd*  
Risk Assessment Branch III (RAB3)  
Health Effects Division (HED; 7509P)

THROUGH: Julie L. Van Alstine, MPH, Environmental Health Scientist *Julie Van Alstine*  
Sheila Piper, Chemist *Sheila Piper*  
Dietary Exposure Science Advisory Council (DESAC)  
HED (7509P)

and

Jeff Dawson, Acting Branch Chief *Jeff Dawson*  
RAB3/HED (7509P)

TO: Barbara Madden/Andrew Ertman, RM#5  
Registration Division (RD; 7505P)

Executive Summary

Acute and chronic aggregate dietary (food and drinking water) exposure and risk assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID), Version 3.16. This software uses 2003-2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). The analyses were conducted in support of a human health risk assessment for the proposed Section 3 use of emamectin benzoate on cucurbits. This memorandum was reviewed by two peer reviewers of the DESAC, per the current DESAC Standard Operating Procedure (SOP).

Acute Dietary (Food and Drinking Water) Exposure Results and Characterization

A probabilistic acute dietary exposure assessment was conducted. The anticipated residue estimates, used for most crops, were based on field trial data. Tolerance-level residues were used for tree nuts (including pistachios) and cottonseed oil. Pesticide Data Program (PDP) monitoring data for years 2009 and 2010 were used for apples since apple juice had a significant impact on exposure. DEEM default processing factors were used except for commodities with chemical-specific processing studies. Percent crop treated (% CT) data and percent crop treated data for new crops (PCTn) provided by the Biological and Economic Analysis Division (BEAD) in 2012 were used. The estimated drinking water concentrations (EDWCs) of emamectin benzoate were provided by the Environmental Fate and Effects Division (EFED). A drinking water residue distribution based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) modeling of the use on ornamentals was used in the acute assessment.

The acute dietary exposure estimates for food and drinking water using the ornamentals scenario for drinking water are below HED's level of concern at the 99.9<sup>th</sup> percentile of exposure for all population subgroups (36% of the aPAD for the general U.S. population and 60% of the aPAD for children 1-2 years old).

Chronic Dietary (Food and Drinking Water) Exposure Results and Characterization

A somewhat refined chronic dietary exposure assessment was conducted. The anticipated residue estimates, used for most crops, were single point estimates (averages) based on field trial data. Tolerance-level residues were used for tree nuts (including pistachios) and cottonseed oil. DEEM default processing factors were used except for commodities with chemical-specific processing studies. Percent crop treated data and PCTn data provided by BEAD in 2012 were used. The EDWC of 0.150 µg/L (ppb) for the chronic exposure was based on PRZM/EXAMS modeling of the use on ornamentals, which resulted in the highest chronic EDWC considering all proposed/registered uses.

The chronic dietary exposure estimates for food and drinking water using the ornamentals scenario for drinking water are below HED's level of concern for all population



subgroups (7.5% of the cPAD for the general U.S. population and 16% of the cPAD for all infants less than 1 year old).

#### Cancer Dietary (Food and Drinking Water) Exposure Results and Characterization

Emamectin benzoate is classified as "not likely to be carcinogenic to humans" based on the rodent carcinogenicity studies.

### **I. Introduction**

Dietary risk assessment incorporates both exposure and toxicity of a given pesticide. For acute and chronic assessments, the risk is expressed as a percentage of a maximum acceptable dose (i.e., the dose which HED has concluded will result in no unreasonable adverse health effects). This dose is referred to as the population adjusted dose (PAD). The PAD is equivalent to point of departure (POD, NOAEL, LOAEL, c.g.) divided by the required uncertainty or safety factors.

For acute and non-cancer chronic exposures, HED is concerned when estimated dietary risk exceeds 100% of the PAD. References which discuss the acute and chronic risk assessments in more detail are available on the EPA/pesticides web site: "Available Information on Assessing Exposure from Pesticides, A User's Guide," 21-JUN-2000, web link: <http://www.epa.gov/fcdrgstr/EPA-PEST/2000/July/Day-12/6061.pdf>; or see SOP 99.6 (20-AUG-1999).

This revised assessment uses DEEM Version 3.16; the previous assessment (N. Dodd, DP No. D393838, 8/29/12) used the older DEEM Version 2.03. Other than the 8/29/12 memo, the most recent dietary risk assessment for emamectin benzoate was conducted by Nancy Dodd (24-JUL-2008, D347924 and addendum 22-JAN-2009, D360696).

### **II. Residue Information**

**Tolerances:** Tolerances for plant commodities have been established under 40 CFR §180.505(a)(1) for the combined residues of emamectin (a mixture of a minimum of 90% 4'-epi-methylamino-4'-deoxyavermectin B<sub>1a</sub> and maximum of 10% 4'-epi-methylamino-4'-deoxyavermectin B<sub>1b</sub>) and its metabolites 8,9-isomer of the B<sub>1a</sub> and B<sub>1b</sub> component of the parent (8,9-ZMA), or 4'-deoxy-4'-epi-amino-avermectin B<sub>1a</sub> and 4'-deoxy-4'-epi-amino-avermectin B<sub>1b</sub>; 4'-deoxy-4'-epi-amino-avermectin B<sub>1a</sub> (AB<sub>1a</sub>); 4'-deoxy-4'-epi-(N-formyl-N-methyl)amino-avermectin (MFB<sub>1a</sub>); and 4'-deoxy-4'-epi-(N-formyl)amino-avermectin B<sub>1a</sub> (FAB<sub>1a</sub>) at levels ranging from 0.02 ppm to 0.20 ppm.

Tolerances for livestock commodities have been established under 40 CFR §180.505(a)(2) for the combined residues of emamectin (MAB<sub>1a</sub> + MAB<sub>1b</sub> isomers) and the associated 8,9-Z isomers (8,9-ZB<sub>1a</sub> + 8,9-ZB<sub>1b</sub>). The established tolerance levels are 0.010 ppm for the fat of cattle, goat, horse, and sheep; 0.050 ppm for the liver of cattle, goat, horse, and sheep; 0.003 ppm for the meat of cattle, goat, horse, and sheep; 0.020 ppm for the meat byproducts except liver of cattle, goat, horse, and sheep; 0.003 ppm for

hog fat; 0.020 ppm for hog liver; 0.002 ppm for hog meat; 0.005 ppm for hog meat byproducts except liver; and 0.003 ppm for milk. No tolerances have been established for poultry commodities.

**Residues of Concern:** The residues of concern in plants for the tolerance expression and dietary risk assessment are emamectin (MAB<sub>1a</sub> + MAB<sub>1b</sub>), the associated 8,9-Z isomers (8,9-ZB<sub>1a</sub> + 8,9-ZB<sub>1b</sub>), and metabolites/degradates AB<sub>1a</sub>, MFB<sub>1a</sub>, and FAB<sub>1a</sub>. For ruminant commodities, emamectin (MAB<sub>1a</sub> + MAB<sub>1b</sub>) and its 8,9-Z isomers (8,9-ZB<sub>1a</sub> + 8,9-ZB<sub>1b</sub>) are included in the tolerance expression and dietary risk assessment.

#### *Residues in Crops:*

**Acute assessment:** A probabilistic acute dietary exposure assessment was conducted. The anticipated residue estimates, used for most crops, were based on field trial data. The anticipated residues for the cucurbits subgroup 9A are shown in Table 1 below. The maximum residue for cantaloupe (0.0046 ppm) was used for the cucurbits subgroup 9A (*HED Standard Operating Procedures 2000.1*, 9/12/2000). Anticipated residues for the cucurbits subgroup 9B were based on the LOD's for cucumber (0.004 ppm) and squash (0.0061 ppm). Tolerance-level residues were used for tree nuts (including pistachios) and cottonseed oil. Pesticide Data Program (PDP) monitoring data for years 2009 and 2010 were used for apples since apple juice had a significant impact on exposure. DEEM default processing factors were used except for commodities with chemical-specific processing studies. Percent crop treated data and PCTn data provided by the BEAD in 2012 were used.

**Chronic assessment:** A somewhat refined chronic dietary exposure assessment was conducted. The anticipated residue estimates, used for most crops, were single point estimates (averages) based on field trial data. The anticipated residues for cucurbits subgroup 9A are shown in Table 1 below. The average residue for cantaloupe (0.0032 ppm) was used for the cucurbits subgroup 9A (*HED Standard Operating Procedures 2000.1*, 9/12/2000). Anticipated residues for the cucurbits subgroup 9B were based on the LODs for cucumber (0.004 ppm) and squash (0.0061 ppm). Tolerance-level residues were used for tree nuts (including pistachios) and cottonseed oil. DEEM default processing factors were used except for commodities with chemical-specific processing studies. Percent crop treated data and PCTn data provided by BEAD in 2012 were used.

**Table 1. Emamectin Benzoate Anticipated Residues for Cucurbits Subgroup 9A**

|            | No. of Trials | Residues (ppm) <sup>1</sup> |                   |               |                  |                   |                   |                                |
|------------|---------------|-----------------------------|-------------------|---------------|------------------|-------------------|-------------------|--------------------------------|
|            |               | MAB <sub>1a</sub>           | MAB <sub>1b</sub> | 8,9-Z isomers | AB <sub>1a</sub> | MFB <sub>1a</sub> | FAB <sub>1a</sub> | Combined residues <sup>2</sup> |
| Cantaloupe | 4             | 0.0005                      | 0.0005            | 0.0005        | 0.0005           | 0.0005            | 0.0005            | 0.0030                         |
|            | 1             | 0.0011                      | 0.0005            | 0.0005        | 0.0005           | 0.0005            | 0.0005            | 0.0036                         |
|            | 1             | 0.0015                      | 0.0005            | 0.0005        | 0.0005           | 0.0005            | 0.0005            | 0.0040                         |
|            | 1             | 0.0012                      | 0.0005            | 0.0005        | 0.0005           | 0.0005            | 0.0005            | 0.0037                         |
|            | 1             | 0.00075                     | 0.0005            | 0.0005        | 0.0005           | 0.0005            | 0.0005            | 0.0032                         |
|            | 1             | 0.0026                      | 0.0005            | 0.0005        | 0.0005           | 0.0005            | 0.0005            | 0.0051                         |
|            | 1             | 0.0012                      | 0.0005            | 0.0005        | 0.0005           | 0.0005            | 0.0005            | 0.0037                         |
|            | 1             | 0.0012                      | 0.0005            | 0.0005        | 0.0005           | 0.0005            | 0.0005            | 0.0037                         |

<sup>1</sup> The LOQ was 0.001 ppm for each analyte. Per-trial averages were calculated using the 1/2 LOQ for all residues reported as <LOQ.

<sup>2</sup> Combined residues include total emamectin (MAB<sub>1a</sub> and MAB<sub>1b</sub>), its 8,9-Z isomers (8,9-ZB<sub>1a</sub> and 8,9-ZB<sub>1b</sub>), and metabolites/degradates AB<sub>1a</sub>, MFB<sub>1a</sub>, and FAB<sub>1a</sub>. The average is 0.0035 ppm.

Pesticide Data Program (PDP) monitoring data for apples were used in the acute assessment since apple juice has a significant impact on exposure. The total number of apple samples from years 2009 and 2010 was 1278 with no detects at a limit of detection of 0.001 ppm.

**Processed Commodities:** Processing studies are available on apples (MRID 45899801), tomatoes (MRID 46587002), and cottonseed (MRID 44883716). The studies show that residues do not concentrate in apple juice, tomato paste, tomato puree, and cottonseed oil; therefore, a processing factor of 1.0x is used for these commodities. The apple juice result is translated to pear juice (1.0x). DEEM default processing factors are applied to other processed commodities: apples, dried (8.0x); pears, dried (6.25x); tomato juice (1.5x); tomato, dried (14.3x); and beef, meat, dried (1.92x).

**Meat, Milk, Poultry, and Eggs:** Residues in livestock commodities are based on the livestock dietary burdens from Table 2 and the feeding study results from Table 3.

**Table 2. Livestock Maximum Reasonable Dietary Burdens for Emamectin Benzoate<sup>1</sup>**

| Feedstuff               | Type | Tolerance, ppm     | % Dry Matter | % Diet          |       |         |       | Dietary Contributions (ppm) |        |         |        |
|-------------------------|------|--------------------|--------------|-----------------|-------|---------|-------|-----------------------------|--------|---------|--------|
|                         |      |                    |              | Beef            | Dairy | Poultry | Swine | Beef                        | Dairy  | Poultry | Swine  |
| Almond hulls            | R    | 0.055 <sup>1</sup> | 90           | NU <sup>2</sup> | 10    | NU      | NU    | 0                           | 0.0061 | 0       | 0      |
| Cotton gin byproducts   | R    | 0.050              | 90           | 5               | NU    | NU      | NU    | 0.0028                      | 0      | 0       | 0      |
| Cotton hulls            | R    | 0.025              | 90           | 10              | NU    | NU      | NU    | 0.0028                      | 0      | 0       | 0      |
| Untreated               | R    | 0                  | ---          | 0               | 35    | 0       | 0     | 0                           | 0      | 0       | 0      |
| Apple pomace, wet       | CC   | 0.075              | 40           | NU <sup>3</sup> | 10    | NU      | NU    | 0                           | 0.019  | 0       | 0      |
| Untreated               | CC   | 0                  | --           | 80              | 35    | 75      | 85    | 0                           | 0      | 0       | 0      |
| Cotton meal             | PC   | 0.025              | 89           | 5               | --    | 20      | 15    | 0.0014                      | 0      | 0.0056  | 0.0042 |
| Cotton, undelinted seed | PC   | 0.025              | 88           | NU              | 10    | NU      | NU    | 0                           | 0.0028 | 0       | 0      |
| Untreated               | PC   | 0                  | ---          | 0               | 0     | 5       | 0     | 0                           | 0      | 0       | 0      |
| <b>Totals</b>           |      |                    |              | 100             | 100   | 100     | 100   | 0.0070                      | 0.028  | 0.0056  | 0.0042 |

<sup>1</sup> All data are based on *Table 1 Feedsuffs* (June 2008). Residue levels for beef and dairy cattle are corrected for moisture content and are determined by the following formula: tolerance ÷ % dry matter × % in diet. Residue levels for poultry and swine are considered "as-is" and are determined by the following formula: tolerance × % in diet.

<sup>2</sup> NU = Not Used.

<sup>3</sup> Almond hulls are partially blended. The average residue value (0.055 ppm from MRID 47243301) is used for dairy cattle feed items. The HAF of 0.0985 ppm would be used for beef cattle, poultry, or swine.

An adequate cattle feeding study was submitted in conjunction with a previous petition (PP#7F04845, D267346, M. Xue, 2/19/02). The maximum residues observed in cattle matrices at each of the dosing levels are presented in Table 3 below. The reported LODs and LOQs for each analyte were 0.001 and 0.002 ppm, respectively, in liver, kidney, muscle, and fat; 0.0001 and 0.0005 ppm, respectively, in milk (whole and skim); and 0.00025 and 0.0005 ppm, respectively, in cream.

Since all dietary burdens in Table 2 above are <0.03 ppm, the residues from the low dose (0.03 ppm) cattle feeding study were used in the dietary assessments as the residue levels in livestock commodities. Component residues used in the dietary assessment for whole milk and cream are bolded in Table 3 below. Component residues used for fat, kidney, liver, and meat (muscle) are also bolded. For residues reported as <LOD or <LOQ, 1/2 the LOD or 1/2 the LOQ was used to sum the component residues. The total residues used in the assessment were 0.003 ppm for fat, 0.0045 ppm for kidney, 0.01 ppm for liver, 0.002 ppm for meat, and 0.01 ppm for meat byproducts of cattle, goat, hog, horse, and sheep; 0.0003 ppm for milk, and 0.002 ppm for cream. No poultry commodity tolerances have been established.



**Table 3. Maximum Residues Observed in Cattle Matrices in the Cattle Feeding Study<sup>2</sup>**

| Matrix     | Low Dose (0.030 ppm)                         |                                              | Mid Dose (0.090 ppm)                         |                                              | High Dose (0.300 ppm)                        |                                              |
|------------|----------------------------------------------|----------------------------------------------|----------------------------------------------|----------------------------------------------|----------------------------------------------|----------------------------------------------|
|            | MAB <sub>1a</sub> +<br>8,9-Z B <sub>1a</sub> | MAB <sub>1b</sub> +<br>8,9-Z B <sub>1b</sub> | MAB <sub>1a</sub> +<br>8,9-Z B <sub>1a</sub> | MAB <sub>1b</sub> +<br>8,9-Z B <sub>1b</sub> | MAB <sub>1a</sub> +<br>8,9-Z B <sub>1a</sub> | MAB <sub>1b</sub> +<br>8,9-Z B <sub>1b</sub> |
| Whole milk | <0.0005                                      | <0.0001                                      | 0.0010                                       | <0.0005                                      | 0.0053                                       | 0.0006 <sup>1</sup>                          |
| Skim milk  | <0.0005                                      | <0.0001                                      | 0.0007                                       | <0.0001                                      | 0.0030                                       | <0.0005                                      |
| Cream      | 0.0021                                       | <0.0001                                      | 0.0046                                       | <0.0005                                      | 0.021                                        | 0.0017 <sup>1</sup>                          |
| Fat        | 0.0022                                       | <0.001                                       | 0.0066                                       | <0.002                                       | 0.015                                        | <0.002                                       |
| Kidney     | 0.0040                                       | <0.001                                       | 0.013                                        | <0.001                                       | 0.042                                        | 0.0036 <sup>1</sup>                          |
| Liver      | 0.010                                        | <0.001                                       | 0.029                                        | 0.0022                                       | 0.115                                        | 0.0090 <sup>1</sup>                          |
| Muscle     | <0.002                                       | <0.001                                       | 0.0020                                       | <0.001                                       | 0.0064                                       | <0.001                                       |

<sup>1</sup> This value represents the result for MAB<sub>1b</sub> + 8,9-Z B<sub>1b</sub> in the sample containing the maximum residues of MAB<sub>1a</sub> + 8,9-Z B<sub>1a</sub>.

<sup>2</sup> Component residues used in the dietary assessment are bolded. For residues reported as <LOD or <LOQ, ½ the LOD or ½ the LOQ was used to sum the component residues.

**Catfish Fish:** The USDA Pesticide Data Program (PDP) monitored pesticide residues in catfish/fish in 2008, 2009, and 2010; however, the samples were not analyzed for emamectin benzoate. As a result, residues in catfish/fish were not included in the assessment.

#### Residue Data used for the Acute Dietary (Food + Drinking Water) Assessment:

A probabilistic acute dietary exposure assessment was conducted. The anticipated residue estimates, used for most crops, were based on field trial data. The anticipated residues for the cucurbits subgroup 9A are shown in Table 1 above. The maximum residue for cantaloupe (0.0051 ppm) was used for the cucurbits subgroup 9A (*HEID Standard Operating Procedures 2000.1*, 9/12/2000). Anticipated residues for the cucurbits subgroup 9B were based on the LOD's for cucumber (0.004 ppm) and squash (0.0061 ppm). Tolerance-level residues were used for tree nuts (including pistachios) and cottonseed oil. Pesticide Data Program (PDP) monitoring data for years 2009 and 2010 were used for apples since apple juice had a significant impact on exposure. DEEM default processing factors were used except for commodities with available chemical-specific processing studies. Percent crop treated data and PCTn data provided by BEAD in 2012 were used. The EDWCs of emamectin benzoate were provided by EFED. A drinking water residue distribution based on the PRZM/EXAMS modeling of the use on ornamentals was used in the acute assessment.

#### Residue Data used for the Chronic Dietary (Food + Drinking Water) Assessment:

A somewhat refined chronic dietary exposure assessment was conducted. The anticipated residue estimates, used for most crops, were single point estimates (averages) based on field trial data. The anticipated residues for cucurbits subgroup 9A are shown in Table 1 above. The average residue for cantaloupe (0.0035 ppm) was used for the cucurbits subgroup 9A (*HEID Standard Operating Procedures 2000.1*, 9/12/2000). Anticipated residues for the cucurbits subgroup 9B were based on the LODs for cucumber (0.004 ppm) and squash (0.0061 ppm). Tolerance-level residues were used for tree nuts (including pistachios) and cottonseed oil. DEEM default processing factors were used except for commodities with chemical-specific processing studies. Percent crop treated data and PCTn data provided by BEAD in 2012 were used. The EDWC of 0.150 µg/L (ppb) for the chronic exposure was based on PRZM/EXAMS modeling of the use on ornamentals, which resulted in the highest chronic EDWC considering all proposed/registered uses.

### **III. Percent Crop Treated Information**

A screening level usage analysis (SLUA) dated 5/29/12 was provided by BEAD based on data years 2003-2010. A PCTn analysis was also provided by BEAD (DP#403689, J. Alsadek, Ph.D., 8/21/12). (Refer to Attachment 2). The estimated maximum percent crop treated for each of sixteen crops was used for the acute dietary risk assessment and the estimated weighted average percent crop treated was used for the chronic dietary risk assessment.

The following maximum percent crop treated estimates (SLUA, 5/29/12) were used in the acute dietary risk assessment for the following crops that are currently registered for emamectin benzoate: almonds: 2.5%; apples: 20%; broccoli: 20%; cabbage: 25%; cauliflower: 20%; celery: 40%; cotton: 2.5%; lettuce: 20%; pears: 20%; peppers: 15%; spinach: 10%; and tomatoes: 20%.

The following maximum PCTn estimates (DP#403689, J. Alsadek, Ph.D., 8/21/12) were used in the dietary risk assessment for the following crops that are the subject of this petition for residues of emamectin benzoate: cantaloupe: 51%; cucumber: 26%; squash: 46%; and watermelon: 21%.

The following average percent crop treated estimates (SLUA, 5/29/12) were used in the acute dietary risk assessment for the following crops that are currently registered for emamectin benzoate: almonds: 1%; apples: 10%; broccoli: 5%; cabbage: 10%; cauliflower: 10%; celery: 25%; cotton: 1%; lettuce: 10%; pears: 5%; peppers: 5%; spinach: 5%; and tomatoes: 10%.

The following average PCTn estimates (DP#403689, J. Alsadek, Ph.D., 8/21/12) were used in the dietary risk assessment for the following crops that are the subject of this petition for residues of emamectin benzoate: cantaloupe: 40%; cucumber: 14%; squash: 29%; and watermelon: 19%.

For livestock commodities, percent crop treated for apples was used for beef and dairy cattle; percent crop treated for cotton (the only poultry/swine feed item) was used for swine.

#### IV. Drinking Water Data

The drinking water residues used in the dietary risk assessment were provided by EFED in the following memorandum: "Amended Drinking Water Assessment for the proposed use of Emamectin Benzoate on outdoor ornamentals and Group 9 cucurbit vegetables" (DP#402307, Tiffany Downen, 5/30/12) and incorporated directly into this dietary assessment. Water residues were incorporated in the DEEM-FCID into the food categories "water, direct, all sources" and "water, indirect, all sources."

EFED provided EDWCs for the proposed/registered uses of emamectin benzoate including the proposed uses on outdoor ornamentals (EPA 100-RURR) and cucurbit vegetables (EPA 100-904). EDWCs from use on outdoor-grown ornamentals are the highest. Emamectin benzoate residues (parent + degradation products), based on applications made to ornamentals and group 9 cucurbits, are not expected to exceed 0.465 µg/L for the 1 in 10 year daily peak, 0.150 µg/L for the 1 in 10 year annual average, and 0.112 µg/L for the 30 year annual average (Table 4). A distribution of drinking water numbers using the ornamentals scenario was used in the acute assessment. The EDWC of 0.150 µg/L was used in the chronic assessment.

The Agency identified four degradates of concern based on structural similarity to emamectin benzoate that are formed via photolysis (MARC memo references: D238206, Sept 2, 1997; D255357, Aug 20, 2001; D277085, Aug 20, 2001):

- (8,9-Z)-4"-epimethylamino-4"-deoxy avermectin B1 (8,9 ZMA isomer);
- 4"-epiamino-4"-deoxyavermectin B1 (AB);
- avermectin B1 monosaccharide (MAB); and
- 4"-epi-(N-formyl)-4"-deoxyavermectin B1 (FAB).

These degradates were included in the drinking water assessment for emamectin benzoate and are assumed to be of equal or lesser toxicity to that of the parent compound. The total toxic residues approach is used for determining the environmental fate data parameters for modeling using the *Guidance for Selecting Input Parameters in Modeling the Environmental Fate and Transport of Pesticides*, Version 2.1, October 22, 2009, and the draft *Guidance for Modeling Pesticides Total Toxic Residues (TTR)*, dated May 20, 2009.

Table 4. EDWCs for Emamectin Benzoate Residues from Use on Outdoor Ornamentals and Group 9 Cucurbit Vegetables<sup>1</sup>

| Use                                     | Model                   | 1 in 10 year            |                         | 30 year Annual Average  |
|-----------------------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
|                                         |                         | Peak                    | Annual Mean             |                         |
| µg/L                                    |                         |                         |                         |                         |
| Surface Water                           |                         |                         |                         |                         |
| Ornamentals                             | PRZM/EXAMS <sup>2</sup> | 0.465                   | 0.150                   | 0.112                   |
| Ground Water                            |                         |                         |                         |                         |
| Ornamentals/Group 9 Cucurbit Vegetables | SCI-GROW                | 0.54 x 10 <sup>-3</sup> | 0.54 x 10 <sup>-3</sup> | 0.54 x 10 <sup>-3</sup> |

<sup>1</sup> Degradates of concern included in the calculation of EDWCs: (8,9-Z)-4"-epimethylamino-4"-deoxy avermectin B1, 4"-epiamino-4"-deoxyavermectin B1, avermectin B1 monosaccharide, and 4"-epi-(N-formyl)-4"-deoxyavermectin B1 (the 8,9 ZMA isomer, AB, MAB, and FAB, respectively).

<sup>2</sup> Typically, the values generated by the models for drinking water are multiplied by a percent crop area factor (PCA). The PCA accounts for the fact that it is unlikely for any basin to be completely planted to agricultural crops. The PCA adjustment factor is assumed to be 0.87 for the group 9 cucurbit vegetables and 1.0 for the outdoor ornamentals crops as per the PCA guidance.

The model and its description are available at the EPA internet site:  
<http://www.epa.gov/oppefed1/models/water/>.

#### V. DEEM-FCID™ Program and Consumption Information

Emamectin benzoate acute and chronic dietary exposure assessments were conducted using DEEM-FCID, Version 3.16, which incorporates 2003-2008 consumption data from USDA's NHANES/WWEIA. The data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods "as consumed" (e.g., apple pie) are linked to EPA-defined food commodities (e.g. apples, peeled fruit - cooked; fresh or N/S; baked; or wheat flour - cooked; fresh or N/S, baked) using publicly available recipe translation files developed jointly by USDA/ARS and EPA. For chronic exposure assessment, consumption data are averaged for the entire U.S. population and within population subgroups. However, for acute exposure assessment, consumption data are retained as individual consumption events. Based on analysis of the 2003-2008 WWEIA consumption data, which took into account dietary patterns and survey respondents, HED concluded that it is most appropriate to report risk for the following population subgroups: the general U.S. population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, adults 20-49, females 13-49, and adults 50-99 years old.

For chronic dietary exposure assessment, an estimate of the residue level in each food or food-form (e.g., orange or orange juice) on the food commodity residue list is multiplied by the average daily consumption estimate for that food/food form to produce a residue intake estimate. The resulting residue intake estimate for each food/food form is summed with the residue intake estimates for all other food/food forms on the commodity residue



list to arrive at the total average estimated exposure. Exposure is expressed in mg/kg body weight/day and as a percent of the cPAD. This procedure is performed for each population subgroup.

For acute exposure assessments, individual one-day food consumption data are used on an individual-by-individual basis. The reported consumption amounts of each food item can be multiplied by a residue point estimate and summed to obtain a total daily pesticide exposure for a deterministic exposure assessment, or "matched" in multiple random pairings with residue values and then summed in a probabilistic assessment. The resulting distribution of exposures is expressed as a percentage of the aPAD on both a user (i.e., only those who reported eating relevant commodities/food forms) and a per-capita (i.e., those who reported eating the relevant commodities as well as those who did not) basis. In accordance with HED policy, per capita exposure and risk are reported for analyses performed at all levels of refinement. However, for deterministic assessments, any significant differences in user vs. per capita exposure and risk are specifically identified and noted in the risk assessment.

## VI. Toxicological Information

The HED Risk Assessment Team confirmed endpoints that were previously selected (*Emamectin Benzoate, Human Health Assessment Scoping Document in Support of Registration Review*, D385990, N. Dodd, N. Tsaur, and W. Phang, 6/16/11; HIARC's February 26, 1998, July 28 and August 3, 1998, and March 5, 2003 evaluations of the emamectin toxicity database). The endpoints and uncertainty factors (UFs) selected by HED's HIARC in 2003 remain unchanged; however, under the current data requirement guidelines, immunotoxicity data (OCSPP 870.7800) and a subchronic inhalation study (OCSPP 870.3465) are required.

Although HED concluded that there is a low degree of concern and lack of residual uncertainties for pre- and post-natal toxicity, the 10X FQPA safety factor (SF) is retained for chronic assessments while a 3X FQPA SF is adequate for acute assessments.

A 10X FQPA SF has been retained for the chronic assessment to account for the steepness of the dose response curve, severity of effects at the LOAEL (death and neuropathology), and most importantly the use of a short-term study for long term risk assessment. The 10X FQPA SF will also provide adequate protection for the lack of the new immunotoxicity study. A 3X FQPA SF has been retained for the acute assessment to account for the steepness of the dose-response curve and severity of effects at the LOAEL (death and neuropathology).

The doses and toxicological endpoints selected for use in dietary exposure assessments are summarized in Table 5.

**Table 5. Summary of Toxicological Doses and Endpoints for Emamectin benzoate for Use in Dietary Exposure Assessments**

| Exposure/Scenario                 | Point of Departure                                                                                                                                            | Uncertainty/FQPA Safety Factors                                 | RfD, PAD, Level of Concern for Risk Assessment                    | Study and Toxicological Effects                                                                                                                                                                               |
|-----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|-------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Acute Dietary (All Populations)   | NOAEL = 0.075 mg/kg/day                                                                                                                                       | UF <sub>A</sub> = 10x<br>UF <sub>H</sub> = 10x<br>FQPA SF = 3x  | Acute RfD = 0.00025 mg/kg/day<br><br>aPAD = 0.00025 mg/kg/day     | <b>15-day mouse</b><br>LOAEL = 0.1 mg/kg/day based on tremors on day 3 of dosing.                                                                                                                             |
| Chronic Dietary (All Populations) | NOAEL = 0.075 mg/kg/day                                                                                                                                       | UF <sub>A</sub> = 10x<br>UF <sub>H</sub> = 10x<br>FQPA SF = 10x | Chronic RfD = 0.000075 mg/kg/day<br><br>cPAD = 0.000075 mg/kg/day | <b>15-day mouse</b><br>LOAEL = 0.1 mg/kg/day based on moribund sacrifices, clinical signs of neurotoxicity, decreases in body weight and food consumption and histopathological lesions in the sciatic nerve. |
| Cancer (oral, dermal, inhalation) | Classification: "Not likely to be Carcinogenic to Humans" based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies. |                                                                 |                                                                   |                                                                                                                                                                                                               |

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose.

## VII. Results/Discussion

As stated above, for acute and chronic assessments, HED is concerned when dietary risk exceeds 100% of the PAD. The DEEM-FCID analyses estimate the dietary exposure of the U.S. population and various population subgroups. The results reported in Tables 6 and 7 are for the general U.S. Population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, females 13-49, adults 20-49, and adults 50-99 years.

### Results of Acute Dietary (Food and Drinking Water) Exposure Analysis

The results of the acute dietary (food + drinking water) exposure analysis at the 95<sup>th</sup>, 99<sup>th</sup>, and 99.9<sup>th</sup> percentiles of exposure are reported in Table 6. The emamectin benzoate acute dietary risk estimates for food and drinking water using the ornamental scenario for drinking water are below HED's level of concern (<100% aPAD) at the 99.9<sup>th</sup> percentile of exposure for the general U.S. population and all population subgroups, at 36% of the aPAD for the general U.S. population and 60% of the aPAD for children 1-2 years old, the most highly exposed subgroup.

| Table 6. Results of Acute Dietary (Food and Drinking Water) Exposure Analysis Using DEEM FCID <sup>1</sup> |                     |                             |           |                             |           |                               |           |
|------------------------------------------------------------------------------------------------------------|---------------------|-----------------------------|-----------|-----------------------------|-----------|-------------------------------|-----------|
| Population Subgroup                                                                                        | aPAD<br>(mg/kg/day) | 95 <sup>th</sup> Percentile |           | 99 <sup>th</sup> Percentile |           | 99.9 <sup>th</sup> Percentile |           |
|                                                                                                            |                     | Exposure<br>(mg/kg/day)     | %<br>aPAD | Exposure<br>(mg/kg/day)     | %<br>aPAD | Exposure<br>(mg/kg/day)       | %<br>aPAD |
| General U.S. Population                                                                                    | 0.00025             | 0.000019                    | 7.4       | 0.000038                    | 15        | 0.000091                      | 36        |
| All Infants (< 1 year old)                                                                                 |                     | 0.000037                    | 15        | 0.000070                    | 28        | 0.000138                      | 55        |
| <b>Children 1-2 years old</b>                                                                              |                     | 0.000038                    | 15        | 0.000074                    | 29        | <b>0.000151</b>               | <b>60</b> |
| Children 3-5 years old                                                                                     |                     | 0.000028                    | 11        | 0.000059                    | 23        | 0.000135                      | 54        |
| Children 6-12 years old                                                                                    |                     | 0.000018                    | 7.3       | 0.000042                    | 17        | 0.000082                      | 33        |
| Youth 13-19 years old                                                                                      |                     | 0.000012                    | 4.8       | 0.000025                    | 10        | 0.000084                      | 33        |
| Adults 20-49 years old                                                                                     |                     | 0.000016                    | 6.5       | 0.000032                    | 13        | 0.000077                      | 31        |
| Adults 50-99 years old                                                                                     |                     | 0.000018                    | 7.3       | 0.000035                    | 14        | 0.000093                      | 37        |
| Females 13-49 years old                                                                                    |                     | 0.000016                    | 6.5       | 0.000033                    | 13        | 0.000076                      | 30        |

<sup>1</sup>The population with the highest exposure is bolded.

#### Results of Chronic Dietary (Food and Drinking Water) Exposure Analysis

The results of the chronic dietary (food and drinking water) exposure analysis are reported in the summary table below. For the chronic dietary assessment, all population subgroups have risk estimates which are below HED's level of concern. The emamectin benzoate chronic dietary risk estimates for food and drinking water using the ornamental scenario for drinking water are below HED's level of concern for the general U.S. population and all population subgroups, at 7.5% of the cPAD for the general U.S. population and 16% of the cPAD for all infants (<1 year old), the most highly exposed subgroup.

| Table 7. Summary of Dietary (Food and Drinking Water) Exposure and Risk for Emamectin Benzoate |                                                  |           |                                 |         |
|------------------------------------------------------------------------------------------------|--------------------------------------------------|-----------|---------------------------------|---------|
| Population Subgroup                                                                            | Acute Dietary<br>(95.9 <sup>th</sup> Percentile) |           | Chronic Dietary                 |         |
|                                                                                                | Dietary Exposure<br>(mg/kg/day)                  | % aPAD*   | Dietary Exposure<br>(mg/kg/day) | % cPAD* |
| General U.S. Population                                                                        | 0.000091                                         | 36        | 0.000006                        | 7.5     |
| All Infants (<1 year old)*                                                                     | 0.000138                                         | 55        | 0.000012                        | 16      |
| Children 1-2 years old*                                                                        | <b>0.000151</b>                                  | <b>60</b> | 0.000011                        | 15      |
| Children 3-5 years old                                                                         | 0.000135                                         | 54        | 0.000009                        | 12      |
| Children 6-12 years old                                                                        | 0.000082                                         | 33        | 0.000006                        | 7.4     |
| Youth 13-19 years old                                                                          | 0.000084                                         | 33        | 0.000004                        | 5.2     |
| Adults 20-49 years old                                                                         | 0.000077                                         | 31        | 0.000005                        | 6.9     |
| Adults 50-99 years old                                                                         | 0.000093                                         | 37        | 0.000006                        | 7.7     |
| Females 13-49 years old                                                                        | 0.000076                                         | 30        | 0.000005                        | 6.8     |

\*The subpopulations with the highest risk estimates are bolded.

#### VIII. Characterization of Inputs/Outputs

The acute and chronic assessments for food incorporate somewhat refined anticipated residue estimates for most commodities that were derived from field trial data and %CT/PCTn data. Monitoring data were used for apples in the acute assessment since apple juice had a significant impact on exposure. The use of more monitoring data and food preparation-reduction factors for washing, cooking, etc. may have resulted in more refined estimates of dietary exposure. More highly refined analyses are not needed at this time since the risk estimates are below HED's level of concern.

#### IX. Conclusions

The acute dietary exposure assessment is a probabilistic assessment conducted for all proposed/registered food uses of emamectin benzoate and drinking water. The anticipated residue estimates used for most crops were based on field trial data, incorporated percent crop treated or PCTn estimates provided by BEAD, and processing factors where appropriate. PDP monitoring data were used for apples. A drinking water residue distribution based on the use on ornamentals was used in the acute assessment. The acute dietary exposure estimates for food and drinking water are below HED's level of concern at the 99.9<sup>th</sup> percentile of exposure for all population subgroups (36% of the aPAD for the general U.S. population and 60% of the aPAD for children 1-2 years old).



The chronic dietary exposure assessment is a somewhat refined assessment conducted for all proposed/registered food uses of emamectin benzoate and drinking water. The anticipated residue estimates used for most crops were single point estimates (averages) based on field trial data, incorporated percent crop treated or PCTn estimates provided by BEAD, and processing factors where appropriate. An EDWC based on the use on ornamentals was used in the chronic assessment. The chronic dietary exposure estimates for food and drinking water are below HED's level of concern for all population subgroups (7.5% of the cPAD for the general U.S. population and 16% of the cPAD for all infants less than 1 year old).

## X. List of Attachments

Attachment 1: Acute Residue Distribution Files and Chronic Point Estimates.  
Attachment 2: Percent Crop Treated Memos from BEAD.  
Attachment 3: Acute Food plus Water Residue Input File.  
Attachment 4: Acute Results File.  
Attachment 5: Chronic Food plus Water Residue Input File.  
Attachment 6: Chronic Results File.

cc: N. Dodd

## Attachment 1: Acute Residue Distribution Files and Chronic Point Estimates

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                      |                                                                                                                                        |                                                                                                                                                                                        |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>RDF 1<br/>'Apple, PDP Data, 20%CT<br/>TOTALZ=1022<br/>TOTALLOD=256<br/>LODRES=0.0005</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <p>RDF 2<br/>'Bell Pepper<br/>Field trial data 15%CT<br/>TOTALZ=17<br/>TOTALNZ=3</p> | <p>RDF 3<br/>'Broccoli<br/>Field trial data 20%CT<br/>TOTALZ=48<br/>TOTALNZ=12</p>                                                     | <p>RDF 4<br/>'Cabbage<br/>Field trial data 25%CT<br/>TOTALZ=54<br/>TOTALNZ=18</p>                                                                                                      |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <p>0.010<br/>0.010<br/>0.010</p>                                                     | <p>0.002<br/>0.002<br/>0.002<br/>0.002<br/>0.002<br/>0.002<br/>0.002<br/>0.002<br/>0.002<br/>0.004<br/>0.004<br/>0.0064<br/>0.0045</p> | <p>0.002<br/>0.002<br/>0.002<br/>0.002<br/>0.002<br/>0.002<br/>0.002<br/>0.002<br/>0.002<br/>0.002<br/>0.002<br/>0.002<br/>0.002<br/>0.002<br/>0.002<br/>0.002<br/>0.004<br/>0.004</p> |
| <p>Chronic Apple Field Trial<br/>data; n = 30</p> <p>0.001556    0.001556<br/>0.001556    0.001556<br/>0.001556    0.001556<br/>0.001556    0.001556<br/>0.001556    0.001556<br/>0.001556    0.001556<br/>0.001556    0.001556<br/>0.001556    0.001556<br/>0.001556    0.001556<br/>0.001556    0.001556<br/>0.001556    0.001556<br/>0.001556    0.001556<br/>0.001556    0.001556<br/>0.001556    0.001556<br/>0.001556    0.001556<br/>0.001556    0.001556<br/>0.001556    0.001556<br/>0.001556    0.009055<br/>0.001556    0.007055</p> <p>Chronic= 0.0020 x 0.10=<br/>0.00020</p> | <p>Chronic= 0.010 x 0.05<br/>= 0.0005</p>                                            | <p>Chronic= 0.003 x 0.05=<br/>0.00015</p>                                                                                              | <p>Chronic= 0.002 x 0.10=<br/>0.0002</p>                                                                                                                                               |

| RDF 5<br>'Cauliflower'<br>Field trial data 20%CT<br>TOTALZ=48<br>TOTALNZ=12 | RDF 6<br>'Celery'<br>Field trial data 40%CT<br>TOTALZ=32<br>TOTALNZ=21 | RDF 7<br>'Lettuce-head'<br>Field trial data 20%CT<br>TOTALZ=68<br>TOTALNZ=17 | RDF 8<br>'Lettuce-leaf'<br>Field trial data 20%CT<br>TOTALZ=80<br>TOTALNZ=20 |
|-----------------------------------------------------------------------------|------------------------------------------------------------------------|------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| 0.002                                                                       | 0.008                                                                  | 0.002                                                                        | 0.01                                                                         |
| 0.002                                                                       | 0.008                                                                  | 0.002                                                                        | 0.01                                                                         |
| 0.002                                                                       | 0.006                                                                  | 0.002                                                                        | 0.01                                                                         |
| 0.002                                                                       | 0.006                                                                  | 0.002                                                                        | 0.01                                                                         |
| 0.002                                                                       | 0.006                                                                  | 0.002                                                                        | 0.01                                                                         |
| 0.002                                                                       | 0.006                                                                  | 0.002                                                                        | 0.01                                                                         |
| 0.002                                                                       | 0.004                                                                  | 0.002                                                                        | 0.01                                                                         |
| 0.002                                                                       | 0.004                                                                  | 0.002                                                                        | 0.012                                                                        |
| 0.002                                                                       | 0.002                                                                  | 0.002                                                                        | 0.012                                                                        |
| 0.002                                                                       | 0.0082                                                                 | 0.002                                                                        | 0.014                                                                        |
| 0.002                                                                       | 0.0069                                                                 | 0.006                                                                        | 0.014                                                                        |
| 0.004                                                                       | 0.0121                                                                 | 0.006                                                                        | 0.0114                                                                       |
|                                                                             | 0.0104                                                                 | 0.006                                                                        | 0.028                                                                        |
|                                                                             | 0.0055                                                                 | 0.0065                                                                       | 0.025                                                                        |
|                                                                             | 0.0062                                                                 | 0.004                                                                        | 0.033                                                                        |
|                                                                             | 0.0066                                                                 | 0.0067                                                                       | 0.047                                                                        |
|                                                                             | 0.0048                                                                 | 0.0063                                                                       | 0.011                                                                        |
|                                                                             | 0.0054                                                                 |                                                                              | 0.018                                                                        |
|                                                                             | 0.0083                                                                 |                                                                              | 0.017                                                                        |
|                                                                             | 0.0075                                                                 |                                                                              | 0.039                                                                        |
|                                                                             | 0.0044                                                                 |                                                                              |                                                                              |
| Chronic= 0.002 x 0.10=<br>0.0002                                            | Chronic= 0.0065 x<br>0.25= 0.0016                                      | Chronic= 0.0036 x<br>0.10= 0.0004                                            | Chronic= 0.017 x 0.10=<br>0.002                                              |

| RDF 9<br>'Mustard greens<br>Field trial data 100%CT<br>TOTALZ=0 | RDF 10<br>'Non-bell peppers<br>Field trial data 15%CT<br>TOTALZ=68<br>TOTALNZ=12 | RDF 11<br>'Pear<br>Field trial data 20%CT<br>TOTALZ=64<br>TOTALNZ=16 | RDF 12<br>'Spinach<br>Field trial data 10%CT<br>TOTALZ=54<br>TOTALNZ=6 |
|-----------------------------------------------------------------|----------------------------------------------------------------------------------|----------------------------------------------------------------------|------------------------------------------------------------------------|
| 0.01                                                            |                                                                                  |                                                                      |                                                                        |
| 0.01                                                            | 0.010                                                                            | 0.001556                                                             | 0.010                                                                  |
| 0.01                                                            | 0.010                                                                            | 0.001556                                                             | 0.010                                                                  |
| 0.01                                                            | 0.010                                                                            | 0.001556                                                             | 0.011                                                                  |
| 0.01                                                            | 0.010                                                                            | 0.001556                                                             | 0.011                                                                  |
| 0.01                                                            | 0.010                                                                            | 0.001556                                                             | 0.011                                                                  |
| 0.01                                                            | 0.010                                                                            | 0.001556                                                             | 0.012                                                                  |
| 0.01                                                            | 0.010                                                                            | 0.001556                                                             |                                                                        |
| 0.01                                                            | 0.010                                                                            | 0.001556                                                             |                                                                        |
| 0.01                                                            | 0.010                                                                            | 0.001556                                                             |                                                                        |
| 0.01                                                            | 0.010                                                                            | 0.001556                                                             |                                                                        |
| 0.01                                                            | 0.010                                                                            | 0.001556                                                             |                                                                        |
| 0.01                                                            | 0.010                                                                            | 0.001556                                                             |                                                                        |
| 0.013                                                           | 0.010                                                                            | 0.008055                                                             |                                                                        |
| 0.013                                                           |                                                                                  | 0.007055                                                             |                                                                        |
| 0.013                                                           |                                                                                  | 0.007055                                                             |                                                                        |
| 0.013                                                           |                                                                                  | 0.007055                                                             |                                                                        |
| 0.014                                                           |                                                                                  |                                                                      |                                                                        |
| 0.016                                                           |                                                                                  |                                                                      |                                                                        |
| 0.1212                                                          |                                                                                  |                                                                      |                                                                        |
| Chronic= 0.017 x 1= 0.02                                        | Chronic= 0.010 x 0.05= 0.0005                                                    | Chronic= 0.0030 x 0.05= 0.00015                                      | Chronic= 0.011 x 0.05= 0.00055                                         |



| RDF 13<br>Tomato Field trial data<br>20%CT<br>TOTALZ=124<br>TOTALNZ=31 | RDF 14<br>Milk [apple 20%CT]<br>TOTALZ=80 | RDF 15<br>Cattle fat [apple<br>20%CT]<br>TOTALZ=80 | RDF 16<br>Cattle liver [apple<br>20%CT]<br>TOTALZ=80 |
|------------------------------------------------------------------------|-------------------------------------------|----------------------------------------------------|------------------------------------------------------|
| 0.001556                                                               | 20,0.0003                                 | 20,0.003                                           | 20,0.01                                              |
| 0.001556                                                               |                                           |                                                    |                                                      |
| 0.001556                                                               |                                           |                                                    |                                                      |
| 0.001556                                                               |                                           |                                                    |                                                      |
| 0.001556                                                               |                                           |                                                    |                                                      |
| 0.001556                                                               |                                           |                                                    |                                                      |
| 0.001556                                                               |                                           |                                                    |                                                      |
| 0.001556                                                               |                                           |                                                    |                                                      |
| 0.001556                                                               |                                           |                                                    |                                                      |
| 0.001556                                                               |                                           |                                                    |                                                      |
| 0.001556                                                               |                                           |                                                    |                                                      |
| 0.001556                                                               |                                           |                                                    |                                                      |
| 0.001556                                                               |                                           |                                                    |                                                      |
| 0.001556                                                               |                                           |                                                    |                                                      |
| 0.001556                                                               |                                           |                                                    |                                                      |
| 0.001556                                                               |                                           |                                                    |                                                      |
| 0.001556                                                               |                                           |                                                    |                                                      |
| 0.001556                                                               |                                           |                                                    |                                                      |
| 0.001556                                                               |                                           |                                                    |                                                      |
| 0.001556                                                               |                                           |                                                    |                                                      |
| 0.001556                                                               |                                           |                                                    |                                                      |
| 0.001556                                                               |                                           |                                                    |                                                      |
| 0.001556                                                               |                                           |                                                    |                                                      |
| 0.001556                                                               |                                           |                                                    |                                                      |
| 0.003556                                                               |                                           |                                                    |                                                      |
| 0.003556                                                               |                                           |                                                    |                                                      |
| 0.003556                                                               |                                           |                                                    |                                                      |
| 0.003556                                                               |                                           |                                                    |                                                      |
| 0.003556                                                               |                                           |                                                    |                                                      |
| 0.003556                                                               |                                           |                                                    |                                                      |
| 0.005                                                                  |                                           |                                                    |                                                      |
| 0.005                                                                  |                                           |                                                    |                                                      |
| Chronic= 0.0022 x 0.10=<br>0.0002                                      | Chronic= 0.0003 x<br>0.10 = 0.00003       | Chronic= 0.003 x 0.10=<br><b>0.0003</b>            | Chronic= 0.01 x 0.10=<br>0.001                       |

|                                                                                                                                                 |                                                                                                                                                             |                                                                                                                                                             |                                                                                                                                                                                              |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| RDF 17<br>'Cattle meat [apple<br>20%CT]<br>TOTALZ=80<br><br>20,0.002                                                                            | RDF 18<br>'Cattle meat byproduct<br>[apple 20%CT]<br>TOTALZ=80<br><br>20,0.01                                                                               | RDF 19<br>'Hog fat [cotton<br>2.5%CT]<br>TOTALZ=97<br><br>3,0.003                                                                                           | RDF 20<br>'Hog liver [cotton<br>2.5%CT]<br>TOTALZ=97<br><br>3,0.01                                                                                                                           |
| Chronic= 0.002 x 0.10=<br>0.0002                                                                                                                | Chronic= 0.01 x 0.10=<br>0.001                                                                                                                              | Chronic = 0.003 x 0.01<br>= 0.00003                                                                                                                         | Chronic = 0.01 x 0.01 =<br>0.0001                                                                                                                                                            |
| RDF 21<br>'Hog meat [cotton<br>2.5%CT]<br>TOTALZ=97<br><br>3,0.002                                                                              | RDF 22<br>'Hog meat bypd [cotton<br>2.5%CT]<br>TOTALZ=97<br><br>3,0.01                                                                                      | RDF 23<br>'Cream [apple 20%CT]<br>TOTALZ=80<br><br>20,0.002                                                                                                 | RDF 24<br>'Cantaloupe<br>Field trial data 51%CT<br>TOTALZ=10<br>TOTALNZ=10<br>0.0030<br>0.0030<br>0.0030<br>0.0030<br>0.0036<br>0.0040<br>0.0037<br>0.0032<br>0.0051<br>0.0037               |
| Chronic = 0.002 x 0.01<br>= 0.00002                                                                                                             | Chronic = 0.01 x 0.01 =<br>0.0001                                                                                                                           | Chronic = 0.002 x 0.10<br>= 0.0002                                                                                                                          | Chronic = 0.0035 x 0.40<br>= 0.0014                                                                                                                                                          |
| RDF 25<br>'Cucumber<br>Field trial data 26%CT<br>TOTALZ=23<br>TOTALNZ=8<br>0.004<br>0.004<br>0.004<br>0.004<br>0.004<br>0.004<br>0.004<br>0.004 | RDF 26<br>'Summer Squash<br>Field trial data 46%CT<br>TOTALZ=9<br>TOTALNZ=8<br>0.0061<br>0.0081<br>0.0081<br>0.0061<br>0.0061<br>0.0061<br>0.0061<br>0.0061 | RDF 27<br>'Winter Squash Field<br>Trial data 46%CT<br>TOTALZ=9<br>TOTALNZ=8<br>0.0061<br>0.0061<br>0.0061<br>0.0061<br>0.0061<br>0.0061<br>0.0061<br>0.0061 | RDF 28<br>'Watermelon<br>Cantaloupe field trial<br>data 21%CT<br>TOTALZ=38<br>TOTALNZ=10<br>0.0030<br>0.0030<br>0.0030<br>0.0030<br>0.0036<br>0.0040<br>0.0037<br>0.0032<br>0.0051<br>0.0037 |
| Chronic = 0.004 x 0.14<br>= 0.00056                                                                                                             | Chronic = 0.0061 x<br>0.29 = 0.0018                                                                                                                         | Chronic = 0.0061 x<br>0.29 = 0.0018                                                                                                                         | Chronic = 0.0035 x 0.19<br>= 0.00066                                                                                                                                                         |

|                                                                       |                                                                          |                                                                                                                                                                                       |                                         |
|-----------------------------------------------------------------------|--------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|
| RDF 29<br>Almond<br>2.5%CT<br>TOTALZ=97<br><br>3,0.02                 | RDF 30<br>'Cattle kidney [apple<br>20%CT]<br>TOTALZ=80<br><br>20, 0.0045 | RDF 31<br>'Subgroup 9A Other<br>Cantaloupe Field Trial<br>data 100%CT<br>TOTALZ=0<br>(.0030<br>(.0030<br>(.0030<br>(.0030<br>(.0036<br>(.0040<br>(.0037<br>(.0032<br>(.0051<br>(.0037 | RDF 32<br>Ornamentals Drinking<br>Water |
| Chronic = $0.02 \times 0.01 = 0.0002$                                 | Chronic = $0.0045 \times 0.10 = 0.00045$                                 | Chronic = $0.0035 \times 1 = 0.0035$                                                                                                                                                  | Chronic = 0.000150                      |
| RDF 33<br>Hog kidney [cotton<br>2.5%CT]<br>TOTALZ=97<br><br>3, 0.0045 |                                                                          |                                                                                                                                                                                       |                                         |
| Chronic = $0.0045 \times 0.01 = 0.000045$                             |                                                                          |                                                                                                                                                                                       |                                         |

Attachment 2: Percent Crop Treated Memos from BEAD

A screening level usage analysis (SLUA) dated 5/29/12 was provided by BEAD based on data years 2003-2010. The following data were excerpted from the 5/29/12 SLUA.

| Screening Level Estimates of Agricultural Uses of Emamectin Benzoate (5/29/12) |                      |         |
|--------------------------------------------------------------------------------|----------------------|---------|
| Crop                                                                           | Percent Crop Treated |         |
|                                                                                | Average              | Maximum |
| Almonds                                                                        | <1                   | <2.5    |
| Apples                                                                         | 10                   | 20      |
| Broccoli                                                                       | 5                    | 20      |
| Cabbage                                                                        | 10                   | 25      |
| Cauliflower                                                                    | 10                   | 20      |
| Celery                                                                         | 25                   | 40      |
| Cotton                                                                         | <1                   | <2.5    |
| Lettuce                                                                        | 10                   | 20      |
| Pears                                                                          | 5                    | 20      |
| Peppers                                                                        | 5                    | 15      |
| Spinach                                                                        | 5                    | 10      |
| Tomatoes                                                                       | 10                   | 20      |

The following PCTn data were provided by BEAD (DP#403689, J. Alsadek, Ph.D., 8/21/12):

| PCTn Data for Agricultural Uses of Emamectin Benzoate (8/21/12) |         |         |
|-----------------------------------------------------------------|---------|---------|
| Crop                                                            | PCTn    |         |
|                                                                 | Average | Maximum |
| Cantaloupe                                                      | 40      | 51      |
| Cucumber                                                        | 14      | 26      |
| Squash                                                          | 29      | 46      |
| Watermelon                                                      | 19      | 21      |



## Attachment 3: Acute Food plus Water Residue Input File

Filename: C:\Documents and Settings\NDODD\My Documents\DEEM Version 3.16\enamectin benzoate 2013\ENAMECTINACUTEUCURBITS121212.R08  
Chemical: Enamectin Benzoate

RfD(Chronic): 0 mg/kg bw/day NOEL(Chronic): 0 mg/kg bw/day  
RfD(Acute): .00025 mg/kg bw/day NOEL(Acute): .075 mg/kg bw/day  
Date created/last modified: 12-19-2012/12:51:40 Program ver. 3.16, 03-08 d  
Comment: General Population; include pome fruits + drinking water

## RDL indices and parameters for Monte Carlo Analysis:

| Index | Dist | Parameter #1 | Param #2 | Param #3 | Comment |
|-------|------|--------------|----------|----------|---------|
|-------|------|--------------|----------|----------|---------|

| #  | Code |                       |  |  |  |
|----|------|-----------------------|--|--|--|
| 1  | 6    | apple.rdf             |  |  |  |
| 2  | 6    | bellpepper.rdf        |  |  |  |
| 3  | 6    | broccoli.rdf          |  |  |  |
| 4  | 6    | cabbage.rdf           |  |  |  |
| 5  | 6    | cauliflower.rdf       |  |  |  |
| 6  | 6    | celery.rdf            |  |  |  |
| 7  | 6    | lettucehead.rdf       |  |  |  |
| 8  | 6    | lettuceleaf.rdf       |  |  |  |
| 9  | 6    | mustardgreen.rdf      |  |  |  |
| 10 | 6    | nonbellpepper.rdf     |  |  |  |
| 11 | 6    | pear.rdf              |  |  |  |
| 12 | 6    | spinach.rdf           |  |  |  |
| 13 | 6    | tomato.rdf            |  |  |  |
| 14 | 6    | milk.rdf              |  |  |  |
| 15 | 6    | cattlefat.rdf         |  |  |  |
| 16 | 6    | cattleliver.rdf       |  |  |  |
| 17 | 6    | cattlemeat.rdf        |  |  |  |
| 18 | 6    | cattlebypd.rdf        |  |  |  |
| 19 | 6    | hogfat.rdf            |  |  |  |
| 20 | 6    | hogliver.rdf          |  |  |  |
| 21 | 6    | hogmeat.rdf           |  |  |  |
| 22 | 6    | hogmeatbypd.rdf       |  |  |  |
| 23 | 6    | cream.RDF             |  |  |  |
| 24 | 6    | cantaloupe.rdf        |  |  |  |
| 25 | 6    | cucumber.rdf          |  |  |  |
| 26 | 6    | Summer squash.rdf     |  |  |  |
| 27 | 6    | Winter squash.rdf     |  |  |  |
| 28 | 6    | watermelon.rdf        |  |  |  |
| 29 | 6    | almond.rdf            |  |  |  |
| 30 | 6    | cattlekidney.rdf      |  |  |  |
| 31 | 6    | Subgroup 9A Other.rdf |  |  |  |
| 32 | 6    | ornamentals DW.rdf    |  |  |  |
| 33 | 6    | hog kidney.rdf        |  |  |  |

| EPA Code   | Crop Grp | Commodity Name         | Def Res (ppm) | Adj. Factors #1 #2 | RDLComment Pnter |
|------------|----------|------------------------|---------------|--------------------|------------------|
| 0401005000 | 4A       | Amaranth, leafy        | 0.012000      | 1.000 1.000        |                  |
| 0401018000 | 4A       | Arugula                | 0.012000      | 1.000 1.000        |                  |
| 0401104000 | 4A       | chrysanthemum, garland | 0.012000      | 1.000 1.000        |                  |
| 0401133000 | 4A       | Cress, garden          | 0.012000      | 1.000 1.000        |                  |
| 0401134000 | 4A       | Cress, upland          | 0.012000      | 1.000 1.000        |                  |
| 0401138000 | 4A       | Dandelion, leaves      | 0.012000      | 1.000 1.000        |                  |
| 0401150000 | 4A       | Endive                 | 0.012000      | 1.000 1.000        |                  |
| 0401204000 | 4A       | Lettuce, head          | 0.006700      | 1.000 1.000        | 7                |
| 0401205000 | 4A       | Lettuce, leaf          | 0.047000      | 1.000 1.000        | 8                |
| 0401248000 | 4A       | Parsley, leaves        | 0.012000      | 1.000 1.000        |                  |
| 0401313000 | 4A       | Radicchio              | 0.006700      | 1.000 1.000        |                  |
| 0401355000 | 4A       | Spinach                | 0.012000      | 1.000 1.000        | 12               |
| 0401355001 | 4A       | Spinach-babyfood       | 0.012000      | 1.000 1.000        |                  |
| 0402076000 | 4B       | Cardoon                | 0.012100      | 1.000 1.000        |                  |
| 0402085000 | 4B       | Celery                 | 0.012100      | 1.000 1.000        | 6                |
| 0402085001 | 4B       | Celery babyfood        | 0.012100      | 1.000 1.000        | 6                |
| 0402086000 | 4B       | Celery, juice          | 0.012100      | 1.000 1.000        | 6                |
| 0402087000 | 4B       | Celtuce                | 0.012100      | 1.000 1.000        |                  |

|                                                    |     |                              |          |              |          |
|----------------------------------------------------|-----|------------------------------|----------|--------------|----------|
| 0402152000                                         | 4B  | Fennel, Florence             | 0.012100 | 1.000 1.000  |          |
| 0402322000                                         | 4B  | Rhubarb                      | 0.012100 | 1.000 1.000  |          |
| 0402367000                                         | 4B  | Swiss chard                  | 0.012100 | 1.000 1.000  |          |
| 0501061000                                         | 5A  | Broccoli                     | 0.006400 | 1.000 1.000  | 3        |
| 0501061001                                         | 5A  | Broccoli babyfood            | 0.006400 | 1.000 1.000  | 3        |
| 0501062000                                         | 5A  | Broccoli, chinese            | 0.006400 | 1.000 1.000  |          |
| 0501064000                                         | 5A  | Brussels sprouts             | 0.004000 | 1.000 1.000  |          |
| 0501069000                                         | 5A  | Cabbage                      | 0.004000 | 1.000 1.000  | 4        |
| 0501071000                                         | 5A  | Cabbage, Chinese, napa       | 0.004000 | 1.000 1.000  |          |
| 0501072000                                         | 5A  | Cabbage, Chinese, mustard    | 0.006400 | 1.000 1.000  |          |
| 0501083000                                         | 5A  | Cauliflower                  | 0.004000 | 1.000 1.000  | 5        |
| 0501196000                                         | 5A  | Kohlrabi                     | 0.004000 | 1.000 1.000  |          |
| 0502063000                                         | 5B  | Broccoli raab                | 0.121200 | 1.000 1.000  | 9        |
| 0502070000                                         | 5B  | Cabbage, Chinese, bok choy   | 0.121200 | 1.000 1.000  | 9        |
| 0502117000                                         | 5B  | Collards                     | 0.121200 | 1.000 1.000  | 9        |
| 0502194000                                         | 5B  | Kale                         | 0.121200 | 1.000 1.000  | 9        |
| 0502229000                                         | 5B  | Mustard greens               | 0.121200 | 1.000 1.000  | 9        |
| 0502318000                                         | 5B  | Rape greens                  | 0.121200 | 1.000 1.000  | 9        |
| 0502389000                                         | 5B  | Turnip, greens               | 0.121200 | 1.000 1.000  | 9        |
| 0801374000                                         | 8A  | Tomatillo                    | 0.005000 | 1.000 1.000  |          |
| 0801375000                                         | 8A  | Tomato                       | 0.005000 | 1.000 1.000  | 13       |
| 0801375001                                         | 8A  | Tomato-babyfood              | 0.005000 | 1.000 1.000  | 13       |
| 0801376000                                         | 8A  | Tomato, paste                | 0.002200 | 1.000 0.200  | B; no    |
| Full comment: B; no concentration (D328149)        |     |                              |          |              |          |
| 0801376001                                         | 8A  | Tomato, paste-babyfood       | 0.002200 | 1.000 0.200  | B        |
| 0801377000                                         | 8A  | Tomato, puree                | 0.002200 | 1.000 0.200  | B; no    |
| Full comment: B; no concentration (D328149)        |     |                              |          |              |          |
| 0801377001                                         | 8A  | Tomato, puree-babyfood       | 0.002200 | 1.000 0.200  | B        |
| 0801378000                                         | 8A  | Tomato, dried                | 0.002200 | 14.300 0.200 | B        |
| 0801378001                                         | 8A  | Tomato, dried-babyfood       | 0.002200 | 14.300 0.200 | B        |
| 0801379000                                         | 8A  | Tomato, juice                | 0.005000 | 1.500 1.000  | 13       |
| 0801380000                                         | 8A  | Tomato, Tree                 | 0.005000 | 1.000 1.000  |          |
| 0802148000                                         | 8BC | Eggplant                     | 0.010000 | 1.000 1.000  |          |
| 0802234000                                         | 8BC | Okra                         | 0.010000 | 1.000 1.000  |          |
| 0802270000                                         | 8B  | Pepper, bell                 | 0.010000 | 1.000 1.000  | 2        |
| 0802270001                                         | 8B  | Pepper, bell-babyfood        | 0.010000 | 1.000 1.000  | 2        |
| 0802271000                                         | 8B  | Pepper, bell, dried          | 0.010000 | 1.000 0.150  | Biende   |
| Full comment: Blended (B)                          |     |                              |          |              |          |
| 0802271001                                         | 8B  | Pepper, bell, dried-babyfood | 0.010000 | 1.000 0.150  | B        |
| 0802272000                                         | 8BC | Pepper, nonbell              | 0.010000 | 1.000 1.000  | 10       |
| 0802272001                                         | 8BC | Pepper, nonbell-babyfood     | 0.010000 | 1.000 1.000  | 10       |
| 0802273000                                         | 8BC | Pepper, nonbell, dried       | 0.010000 | 1.000 0.150  | B        |
| 0901075000                                         | 9A  | Cantaloupe                   | 0.005100 | 1.000 1.000  | 24 LCD = |
| Full comment: LOD = 0.001 x 6; used 1/2 L/G for ND |     |                              |          |              |          |
| 0901187000                                         | 9A  | Honeydew melon               | 0.005100 | 1.000 1.000  | 31       |
| 0901399000                                         | 9A  | Watermelon                   | 0.005100 | 1.000 1.000  | 28       |
| 0901400000                                         | 9A  | Watermelon, juice            | 0.005100 | 1.000 1.000  | 28       |
| 0902021000                                         | 9B  | Balsam pear                  | 0.004000 | 1.000 1.000  |          |
| 0902088000                                         | 9B  | Chayote, fruit               | 0.006100 | 1.000 1.000  |          |
| 0902102000                                         | 9B  | Chinese waxgourd             | 0.004000 | 1.000 1.000  |          |
| 0902135000                                         | 9B  | Cucumber                     | 0.004000 | 1.000 1.000  | 25 LCD = |
| Full comment: LOD = 0.004                          |     |                              |          |              |          |
| 0902308000                                         | 9B  | Pumpkin                      | 0.006100 | 1.000 1.000  |          |
| 0902309000                                         | 9B  | Pumpkin, seed                | 0.006100 | 1.000 1.000  | B        |
| 0902356000                                         | 9B  | Squash, summer               | 0.006100 | 1.000 1.000  | 26 LCD = |
| Full comment: LOD = 0.0061                         |     |                              |          |              |          |
| 0902356001                                         | 9B  | Squash, summer-babyfood      | 0.006100 | 1.000 1.000  | 26       |
| 0902357000                                         | 9B  | Squash, winter               | 0.006100 | 1.000 1.000  | 27       |
| 0902357001                                         | 9B  | Squash, winter-babyfood      | 0.006100 | 1.000 1.000  | 27       |
| 1100007000                                         | 11  | Apple, fruit with peel       | 0.009055 | 1.000 1.000  | 1        |
| 1100008000                                         | 11  | Apple, peeled fruit          | 0.009055 | 1.000 1.000  | 1        |
| 1100008001                                         | 11  | Apple, peeled fruit-babyfood | 0.009055 | 1.000 1.000  | 1        |
| 1100009000                                         | 11  | Apple, dried                 | 0.002000 | 8.000 0.200  | B        |
| 1100009001                                         | 11  | Apple, dried-babyfood        | 0.002000 | 8.000 0.200  | B        |
| 1100010000                                         | 11  | Apple, juice                 | 0.009055 | 1.000 1.000  | 1        |
| 1100010001                                         | 11  | Apple, juice-babyfood        | 0.009055 | 1.000 1.000  | 1        |
| 1100011000                                         | 11  | Apple, sauce                 | 0.009055 | 1.000 1.000  | 1        |
| 1100011001                                         | 11  | Apple, sauce-babyfood        | 0.009055 | 1.000 1.000  | 1        |
| 1100129000                                         | 11  | Crabapple                    | 0.009055 | 1.000 1.000  |          |
| 1100173500                                         | 11  | Goya berry                   | 0.005000 | 1.000 1.000  |          |

|            |     |                                  |          |       |       |    |
|------------|-----|----------------------------------|----------|-------|-------|----|
| 1100210000 | 11  | Loquat                           | 0.008055 | 1.000 | 1.000 |    |
| 1100266000 | 11  | Pear                             | 0.008055 | 1.000 | 1.000 | 11 |
| 1100266001 | 11  | Pear-babyfood                    | 0.008055 | 1.000 | 1.000 | 11 |
| 1100267000 | 11  | Pear, dried                      | 0.003000 | 6.250 | 0.200 | B  |
| 1100268000 | 11  | Pear, juice                      | 0.008055 | 1.000 | 1.000 | 11 |
| 1100268001 | 11  | Pear, juice babyfood             | 0.008055 | 1.000 | 1.000 | 11 |
| 1100310000 | 11  | Quince                           | 0.008055 | 1.000 | 1.000 |    |
| 1400003000 | 14  | Almond                           | 0.020000 | 1.000 | 1.000 | 29 |
| 1400003001 | 14  | Almond-babyfood                  | 0.020000 | 1.000 | 1.000 | 29 |
| 1400004000 | 14  | Almond, oil                      | 0.020000 | 1.000 | 0.025 | B  |
| 1400004001 | 14  | Almond, oil-babyfood             | 0.020000 | 1.000 | 0.025 | B  |
| 1400059000 | 14  | Brazil nut                       | 0.020000 | 1.000 | 1.000 |    |
| 1400068000 | 14  | Butternut                        | 0.020000 | 1.000 | 1.000 |    |
| 1400081000 | 14  | Cashew                           | 0.020000 | 1.000 | 1.000 |    |
| 1400092000 | 14  | Chestnut                         | 0.020000 | 1.000 | 1.000 |    |
| 1400155000 | 14  | Hazelnut                         | 0.020000 | 1.000 | 1.000 |    |
| 1400156000 | 14  | Hazelnut, oil                    | 0.020000 | 1.000 | 1.000 | B  |
| 1400185000 | 14  | Hickory nut                      | 0.020000 | 1.000 | 1.000 |    |
| 1400213000 | 14  | Macadamia nut                    | 0.020000 | 1.000 | 1.000 |    |
| 1400269000 | 14  | Pecan                            | 0.020000 | 1.000 | 1.000 |    |
| 1400278000 | 14  | Pine nut                         | 0.020000 | 1.000 | 1.000 |    |
| 1400282000 | 14  | Pistachio                        | 0.020000 | 1.000 | 1.000 |    |
| 1400391000 | 14  | Walnut                           | 0.020000 | 1.000 | 1.000 |    |
| 2003128000 | 20C | Cottonseed, oil                  | 0.025000 | 1.000 | 0.025 | B  |
| 2003128001 | 20C | Cottonseed, oil-babyfood         | 0.025000 | 1.000 | 0.025 | B  |
| 3100044000 | 31  | Beef, meat                       | 0.002000 | 1.000 | 1.000 | 17 |
| 3100044001 | 31  | Beef, meat-babyfood              | 0.002000 | 1.000 | 1.000 | 17 |
| 3100045000 | 31  | Beef, meat, dried                | 0.002000 | 1.920 | 1.000 | 17 |
| 3100046000 | 31  | Beef, meat byproducts            | 0.010000 | 1.000 | 1.000 | 18 |
| 3100046001 | 31  | Beef, meat byproducts-babyfood   | 0.010000 | 1.000 | 1.000 | 19 |
| 3100047000 | 31  | Beef, fat                        | 0.003000 | 1.000 | 1.000 | 15 |
| 3100047001 | 31  | Beef, fat-babyfood               | 0.003000 | 1.000 | 1.000 | 15 |
| 3100048000 | 31  | Beef, kidney                     | 0.004500 | 1.000 | 1.000 | 33 |
| 3100049000 | 31  | Beef, liver                      | 0.010000 | 1.000 | 1.000 | 16 |
| 3100049001 | 31  | Beef, liver-babyfood             | 0.010000 | 1.000 | 1.000 | 16 |
| 3200169000 | 32  | Goat, meat                       | 0.002000 | 1.000 | 1.000 | 17 |
| 3200170000 | 32  | Goat, meat byproducts            | 0.010000 | 1.000 | 1.000 | 18 |
| 3200171000 | 32  | Goat, fat                        | 0.003000 | 1.000 | 1.000 | 15 |
| 3200172000 | 32  | Goat, kidney                     | 0.004500 | 1.000 | 1.000 | 33 |
| 3200173000 | 32  | Goat, liver                      | 0.010000 | 1.000 | 1.000 | 16 |
| 3300189000 | 33  | Horse, meat                      | 0.002000 | 1.000 | 1.000 | 17 |
| 3400290000 | 34  | Pork, meat                       | 0.002000 | 1.300 | 1.000 | 21 |
| 3400290001 | 34  | Pork, meat-babyfood              | 0.002000 | 1.000 | 1.000 | 21 |
| 3400291000 | 34  | Pork, skin                       | 0.010000 | 1.000 | 1.000 | 22 |
| 3400292000 | 34  | Pork, meat byproducts            | 0.010000 | 1.000 | 1.000 | 22 |
| 3400292001 | 34  | Pork, meat byproducts-babyfood   | 0.010000 | 1.000 | 1.000 | 22 |
| 3400293000 | 34  | Pork, fat                        | 0.003000 | 1.000 | 1.000 | 19 |
| 3400293001 | 34  | Pork, fat-babyfood               | 0.003000 | 1.000 | 1.000 | 19 |
| 3400294000 | 34  | Pork, kidney                     | 0.004500 | 1.000 | 1.000 | 33 |
| 3400295000 | 34  | Pork, liver                      | 0.010000 | 1.000 | 1.000 | 20 |
| 3500339000 | 35  | Sheep, meat                      | 0.002000 | 1.000 | 1.000 | 17 |
| 3500339001 | 35  | Sheep, meat-babyfood             | 0.002000 | 1.000 | 1.000 | 17 |
| 3500340000 | 35  | Sheep, meat byproducts           | 0.010000 | 1.000 | 1.000 | 18 |
| 3500341000 | 35  | Sheep, fat                       | 0.003000 | 1.000 | 1.000 | 15 |
| 3500341001 | 35  | Sheep, fat-babyfood              | 0.003000 | 1.000 | 1.000 | 15 |
| 3500342000 | 35  | Sheep, kidney                    | 0.004500 | 1.000 | 1.000 | 33 |
| 3500343000 | 35  | Sheep, liver                     | 0.010000 | 1.000 | 1.000 | 16 |
| 3600222000 | 36  | Milk, fat                        | 0.002000 | 1.000 | 1.000 | 23 |
| 3600222001 | 36  | Milk, fat-baby food/infant formu | 0.002000 | 1.000 | 1.000 | 23 |
| 3600223000 | 36  | Milk, nonfat solids              | 0.000300 | 1.000 | 1.000 | 14 |
| 3600223001 | 36  | Milk, nonfat solids-baby food/in | 0.000300 | 1.000 | 1.000 | 14 |
| 3600224000 | 36  | Milk, water                      | 0.000300 | 1.000 | 1.000 | 14 |
| 3600224001 | 36  | Milk, water-babyfood/infant form | 0.000300 | 1.000 | 1.000 | 14 |
| 3600225001 | 36  | Milk, sugar (lactose)-baby food/ | 0.000300 | 1.000 | 1.000 | 14 |
| 8601000000 | 86A | Water, direct, all sources       | 0.000465 | 1.000 | 1.000 | 32 |
| 8602000000 | 86B | Water, indirect, all sources     | 0.000465 | 1.000 | 1.000 | 32 |

#### Attachment 4: Acute Results File

U.S. EPA Ver. 3.16, 03 08-d  
DEEM-PCID ACUTE Analysis for EMAMECTIN BENZOATE NHANES 2001-2008 2-Day  
Residue file: EMAMECTINACUTEUCURBITS121212.R08 Adjustment factor #2 used.  
Analysis Date: 12-19-2012/13:04:38 Residue file dated: 12-19-2012/12:51:40  
NOEL (Acute) = 0.075000 mg/kg body-wt/day  
RAC/FF intake summed over 24 hours  
MC iterations = 1000; MC list in residue file; MC seed = 4; RNG = MS VB  
Run Comment: "General Population; include pome fruits + drinking water"

#### Summary calculations- per capita:

| --- 95th Percentile  |        |      | --- 95th Percentile--- |        |      | ---99.9th Percentile--- |        |     |
|----------------------|--------|------|------------------------|--------|------|-------------------------|--------|-----|
| Exposure             | % aRfD | MOE  | Exposure               | % aRfD | MOE  | Exposure                | % aRfD | MOE |
| Total US Population: |        |      |                        |        |      |                         |        |     |
| 0.00009              | 7.44   | 4030 | 0.000038               | 15.14  | 1981 | 0.000091                | 36.15  | 825 |
| All Infants:         |        |      |                        |        |      |                         |        |     |
| 0.000037             | 14.79  | 2027 | 0.000070               | 28.16  | 1065 | 0.000138                | 55.17  | 543 |
| Children 1-2:        |        |      |                        |        |      |                         |        |     |
| 0.000038             | 15.25  | 1967 | 0.000074               | 29.47  | 1018 | 0.000151                | 60.15  | 497 |
| Children 3-5:        |        |      |                        |        |      |                         |        |     |
| 0.000028             | 11.29  | 2657 | 0.000059               | 23.44  | 1279 | 0.000135                | 53.91  | 556 |
| Children 6-12:       |        |      |                        |        |      |                         |        |     |
| 0.000018             | 7.32   | 4099 | 0.000042               | 16.70  | 1796 | 0.000082                | 34.98  | 909 |
| Youth 13-19:         |        |      |                        |        |      |                         |        |     |
| 0.000012             | 4.85   | 6190 | 0.000025               | 10.09  | 2973 | 0.000084                | 33.47  | 896 |
| Adults 20-49:        |        |      |                        |        |      |                         |        |     |
| 0.000016             | 6.52   | 4599 | 0.000032               | 12.96  | 2315 | 0.000077                | 30.78  | 974 |
| Adults 50-99:        |        |      |                        |        |      |                         |        |     |
| 0.000018             | 7.31   | 4104 | 0.000035               | 14.10  | 2127 | 0.000093                | 37.32  | 803 |
| Female 13-49:        |        |      |                        |        |      |                         |        |     |
| 0.000016             | 6.48   | 4627 | 0.000033               | 13.19  | 2274 | 0.000076                | 30.48  | 984 |



Enamectin benzoate  
PC Code: 122806

Dietary Exposure and Risk Assessment

DP Number: D393838

Attachment 5: Chronic Food plus Water Residue Input File

Filename: C:\Documents and Settings\N00DD\My Documents\DEEM Version 3.16\enamectin benzoate 2013\ENAMECTINCHRONICCURBITS 121212.R08  
Chemical: Enamectin Benzoate  
RfD(Chronic): .000075 mg/kg bw/day NOEL(Chronic): .075 mg/kg bw/day  
RfD(Acute): 0 mg/kg bw/day NOEL(Acute): 0 mg/kg bw/day  
Date created/last modified: 12/19/2012/12:52:17 Program ver: 3.16, 03/08/08  
Comment: general Population; include pome fruits + drinking water

| EPA Code   | Crop Grp | Commodity Name               | Def Res (ppm) | Adj. Factors #1 #2 | Comment |
|------------|----------|------------------------------|---------------|--------------------|---------|
| 0401005000 | 4A       | Amaranth, leafy              | 0.011000      | 1.000 1.000        |         |
| 0401018000 | 4A       | Arugula                      | 0.011000      | 1.000 1.000        |         |
| 0401104000 | 4A       | Chrysanthemum, garland       | 0.011000      | 1.000 1.000        |         |
| 0401133000 | 4A       | Cress, garden                | 0.011000      | 1.000 1.000        |         |
| 0401134000 | 4A       | Cress, upland                | 0.011000      | 1.000 1.000        |         |
| 0401138000 | 4A       | Dandelion, leaves            | 0.011000      | 1.000 1.000        |         |
| 0401150000 | 4A       | Endive                       | 0.011000      | 1.000 1.000        |         |
| 0401204000 | 4A       | Lettuce, head                | 0.003600      | 1.000 0.100        |         |
| 0401205000 | 4A       | Lettuce, leaf                | 0.017000      | 1.000 0.100        |         |
| 0401248000 | 4A       | Parsley, leaves              | 0.011000      | 1.000 1.000        |         |
| 0401313000 | 4A       | Radicchio                    | 0.003600      | 1.000 1.000        |         |
| 0401355000 | 4A       | Spinach                      | 0.011000      | 1.000 0.050        |         |
| 0401355001 | 4A       | Spinach-babyfood             | 0.011000      | 1.000 0.050        |         |
| 0402076000 | 4B       | Cardoon                      | 0.006500      | 1.000 1.000        |         |
| 0402085000 | 4B       | Celery                       | 0.006500      | 1.000 0.250        |         |
| 0402085001 | 4B       | Celery-babyfood              | 0.006500      | 1.000 0.250        |         |
| 0402086000 | 4B       | Celery, juice                | 0.006500      | 1.000 0.250        |         |
| 0402087000 | 4B       | Celtuce                      | 0.006500      | 1.000 1.000        |         |
| 0402152000 | 4B       | Fennel, Florence             | 0.006500      | 1.000 1.000        |         |
| 0402322000 | 4B       | Rhubarb                      | 0.006500      | 1.000 1.000        |         |
| 0402367000 | 4B       | Swiss chard                  | 0.006500      | 1.000 1.000        |         |
| 0501061000 | 5A       | Broccoli                     | 0.003000      | 1.000 0.050        |         |
| 0501061001 | 5A       | Broccoli-babyfood            | 0.003000      | 1.000 0.050        |         |
| 0501062000 | 5A       | Broccoli, Chinese            | 0.003000      | 1.000 1.000        |         |
| 0501064000 | 5A       | Brussels sprouts             | 0.002000      | 1.000 0.100        |         |
| 0501069000 | 5A       | Cabbage                      | 0.002000      | 1.000 0.100        |         |
| 0501071000 | 5A       | Cabbage, Chinese, napa       | 0.002000      | 1.000 1.000        |         |
| 0501072000 | 5A       | Cabbage, Chinese, mustard    | 0.003000      | 1.000 1.000        |         |
| 0501083000 | 5A       | Cauliflower                  | 0.002000      | 1.000 0.100        |         |
| 0501196000 | 5A       | Fohlrabi                     | 0.002000      | 1.000 1.000        |         |
| 0502063000 | 5B       | Broccoli raab                | 0.017000      | 1.000 1.000        |         |
| 0502070000 | 5B       | Cabbage, Chinese, bok choy   | 0.017000      | 1.000 1.000        |         |
| 0502117000 | 5B       | Collards                     | 0.017000      | 1.000 1.000        |         |
| 0502194000 | 5B       | Kale                         | 0.017000      | 1.000 1.000        |         |
| 0502229000 | 5B       | Mustard greens               | 0.017000      | 1.000 1.000        |         |
| 0502318000 | 5B       | Rape greens                  | 0.017000      | 1.000 1.000        |         |
| 0502389000 | 5B       | Turnip, greens               | 0.017000      | 1.000 1.000        |         |
| 0801374000 | 8A       | Tomatillo                    | 0.002200      | 1.000 1.000        |         |
| 0801375000 | 8A       | Tomato                       | 0.002200      | 1.000 0.100        |         |
| 0801375001 | 8A       | Tomato-babyfood              | 0.002200      | 1.000 0.100        |         |
| 0801376000 | 8A       | Tomato, paste                | 0.002200      | 1.000 0.100        |         |
| 0801376001 | 8A       | Tomato, paste babyfood       | 0.002200      | 1.000 0.100        |         |
| 0801377000 | 8A       | Tomato, puree                | 0.002200      | 1.000 0.100        |         |
| 0801377001 | 8A       | Tomato, puree babyfood       | 0.002200      | 1.000 0.100        |         |
| 0801378000 | 8A       | Tomato, dried                | 0.002200      | 14.300 0.100       |         |
| 0801378001 | 8A       | Tomato, dried-babyfood       | 0.002200      | 14.300 0.100       |         |
| 0801379000 | 8A       | Tomato, juice                | 0.002200      | 1.000 0.100        |         |
| 0801380000 | 8A       | Tomato, Tree                 | 0.002200      | 1.000 1.000        |         |
| 0802148000 | 8BC      | Eggplant                     | 0.010000      | 1.000 1.000        |         |
| 0802234000 | 8BC      | Okra                         | 0.010000      | 1.000 1.000        |         |
| 0802270000 | 8B       | Pepper, bell                 | 0.010000      | 1.000 0.050        |         |
| 0802270001 | 8B       | Pepper, bell-babyfood        | 0.010000      | 1.000 0.050        |         |
| 0802271000 | 8B       | Pepper, bell, dried          | 0.010000      | 1.000 0.050        |         |
| 0802271001 | 8B       | Pepper, bell, dried-babyfood | 0.010000      | 1.000 0.050        |         |
| 0802272000 | 8BC      | Pepper, nonbell              | 0.010000      | 1.000 0.050        |         |
| 0802272001 | 8BC      | Pepper, nonbell-babyfood     | 0.010000      | 1.000 0.050        |         |

Enamectin benzoate  
PC Code: 122806

Dietary Exposure and Risk Assessment

DP Number: D393838

|                          |     |                                |          |             |       |
|--------------------------|-----|--------------------------------|----------|-------------|-------|
| 0802273000               | 8BC | Pepper, nonbell, dried         | 0.010000 | 1.000 0.050 |       |
| 0901075000               | 9A  | Cantaloupe                     | 0.003500 | 1.000 0.400 |       |
| 0901187000               | 9A  | Honeydew melon                 | 0.003500 | 1.000 1.000 |       |
| 0901399000               | 9A  | Watermelon                     | 0.003500 | 1.000 0.100 |       |
| 0901400000               | 9A  | Watermelon, juice              | 0.003500 | 1.000 0.100 |       |
| 0902021000               | 9B  | Balsam pear                    | 0.004000 | 1.000 1.000 |       |
| 0902088000               | 9B  | Chayote, fruit                 | 0.006100 | 1.000 1.000 |       |
| 0902102000               | 9B  | Chinese waxgourd               | 0.004000 | 1.000 1.000 |       |
| 0902135000               | 9B  | Cucumber                       | 0.004000 | 1.000 0.140 | LOQ = |
| Full comment: LOQ = 0.02 |     |                                |          |             |       |
| 0902308000               | 9B  | Pumpkin                        | 0.006100 | 1.000 1.000 |       |
| 0902309000               | 9B  | Pumpkin, seed                  | 0.006100 | 1.000 1.000 |       |
| 0902356000               | 9B  | Squash, summer                 | 0.006100 | 1.000 0.290 | LOQ = |
| Full comment: LOQ = 0.02 |     |                                |          |             |       |
| 0902356001               | 9B  | Squash, summer-babyfood        | 0.006100 | 1.000 0.290 |       |
| 0902357000               | 9B  | Squash, winter                 | 0.006100 | 1.000 0.290 |       |
| 0902357001               | 9B  | Squash, winter babyfood        | 0.006100 | 1.000 0.290 |       |
| 1100007000               | 11  | Apple, fruit with peel         | 0.002000 | 1.000 0.100 |       |
| 1100008000               | 11  | Apple, peeled fruit            | 0.002000 | 1.000 0.100 |       |
| 1100008001               | 11  | Apple, peeled fruit-babyfood   | 0.002000 | 1.000 0.100 |       |
| 1100009000               | 11  | Apple, dried                   | 0.002000 | 8.000 0.100 |       |
| 1100009001               | 11  | Apple, dried-babyfood          | 0.002000 | 8.000 0.100 |       |
| 1100010000               | 11  | Apple, juice                   | 0.002000 | 1.000 0.100 |       |
| 1100010001               | 11  | Apple, juice-babyfood          | 0.002000 | 1.000 0.100 |       |
| 1100011000               | 11  | Apple, sauce                   | 0.002000 | 1.000 0.100 |       |
| 1100011001               | 11  | Apple, sauce-babyfood          | 0.002000 | 1.000 0.100 |       |
| 1100129000               | 11  | Crabapple                      | 0.002000 | 1.000 1.000 |       |
| 1100173500               | 11  | Goji berry                     | 0.002200 | 1.000 1.000 |       |
| 1100210000               | 11  | Loquat                         | 0.003000 | 1.000 1.000 |       |
| 1100266000               | 11  | Pear                           | 0.003000 | 1.000 0.050 |       |
| 1100266001               | 11  | Pear-babyfood                  | 0.003000 | 1.000 0.050 |       |
| 1100267000               | 11  | Pear, dried                    | 0.003000 | 6.250 0.050 |       |
| 1100268000               | 11  | Pear, juice                    | 0.003000 | 1.000 0.050 |       |
| 1100269000               | 11  | Pear, juice babyfood           | 0.003000 | 1.000 0.050 |       |
| 1100310000               | 11  | Quince                         | 0.003000 | 1.000 1.000 |       |
| 1400003000               | 14  | Almond                         | 0.020000 | 1.000 0.010 |       |
| 1400003001               | 14  | Almond-babyfood                | 0.020000 | 1.000 0.010 |       |
| 1400004000               | 14  | Almond, oil                    | 0.020000 | 1.000 0.010 |       |
| 1400004001               | 14  | Almond, oil-babyfood           | 0.020000 | 1.000 0.010 |       |
| 1400059000               | 14  | Brazil nut                     | 0.020000 | 1.000 1.000 |       |
| 1400068000               | 14  | Butternut                      | 0.020000 | 1.000 1.000 |       |
| 1400081000               | 14  | Cashew                         | 0.020000 | 1.000 1.000 |       |
| 1400092000               | 14  | Chestnut                       | 0.020000 | 1.000 1.000 |       |
| 1400155000               | 14  | Hazelnut                       | 0.020000 | 1.000 1.000 |       |
| 1400156000               | 14  | Hazelnut, oil                  | 0.020000 | 1.000 1.000 |       |
| 1400185000               | 14  | Hickory nut                    | 0.020000 | 1.000 1.000 |       |
| 1400213000               | 14  | Macadamia nut                  | 0.020000 | 1.000 1.000 |       |
| 1400269000               | 14  | Pecan                          | 0.020000 | 1.000 1.000 |       |
| 1400282000               | 14  | Pistachio                      | 0.020000 | 1.000 1.000 |       |
| 1400291000               | 14  | Walnut                         | 0.020000 | 1.000 1.000 |       |
| 2003128000               | 20C | Cottonseed, oil                | 0.025000 | 1.000 0.010 |       |
| 2003128001               | 20C | Cottonseed, oil babyfood       | 0.025000 | 1.000 0.010 |       |
| 3100044000               | 31  | Beef, meat                     | 0.002000 | 1.000 0.100 |       |
| 3100044001               | 31  | Beef, meat-babyfood            | 0.002000 | 1.000 0.100 |       |
| 3100045000               | 31  | Beef, meat, dried              | 0.002000 | 1.920 0.100 |       |
| 3100046000               | 31  | Beef, meat byproducts          | 0.010000 | 1.000 0.100 |       |
| 3100046001               | 31  | Beef, meat byproducts-babyfood | 0.010000 | 1.000 0.100 |       |
| 3100047000               | 31  | Beef, fat                      | 0.003000 | 1.000 0.100 |       |
| 3100047001               | 31  | Beef, fat-babyfood             | 0.003000 | 1.000 0.100 |       |
| 3100048000               | 31  | Beef, kidney                   | 0.004500 | 1.000 0.100 |       |
| 3100049000               | 31  | Beef, liver                    | 0.010000 | 1.000 0.100 |       |
| 3100049001               | 31  | Beef, liver-babyfood           | 0.010000 | 1.000 0.100 |       |
| 3200169000               | 32  | Goat, meat                     | 0.002000 | 1.000 0.100 |       |
| 3200170000               | 32  | Goat, meat byproducts          | 0.010000 | 1.000 0.100 |       |
| 3200171000               | 32  | Goat, fat                      | 0.003000 | 1.000 0.100 |       |
| 3200172000               | 32  | Goat, kidney                   | 0.004500 | 1.000 0.100 |       |
| 3200173000               | 32  | Goat, liver                    | 0.010000 | 1.000 0.100 |       |
| 3300189000               | 33  | Horse, meat                    | 0.002000 | 1.000 0.100 |       |
| 3400290000               | 34  | Pork, meat                     | 0.002000 | 1.000 0.010 |       |
| 3400290001               | 34  | Pork, meat-babyfood            | 0.002000 | 1.000 0.010 |       |

|                |                                  |          |       |       |
|----------------|----------------------------------|----------|-------|-------|
| 3400291000 34  | Pork, skin                       | 0.010000 | 1.000 | 0.010 |
| 3400292000 34  | Pork, meat byproducts            | 0.010000 | 1.000 | 0.010 |
| 3400292001 34  | Pork, meat byproducts-babyfood   | 0.010000 | 1.000 | 0.010 |
| 3400293000 34  | Pork, fat                        | 0.003000 | 1.000 | 0.010 |
| 3400293001 34  | Pork, fat-babyfood               | 0.003000 | 1.000 | 0.010 |
| 3400294000 34  | Pork, kidney                     | 0.004500 | 1.000 | 0.010 |
| 3400295000 34  | Pork, liver                      | 0.010000 | 1.000 | 0.010 |
| 3500339000 35  | Sheep, meat                      | 0.002000 | 1.000 | 0.100 |
| 3500339001 35  | Sheep, meat babyfood             | 0.002000 | 1.000 | 0.100 |
| 3500340000 35  | Sheep, meat byproducts           | 0.010000 | 1.000 | 0.100 |
| 3500341000 35  | Sheep, fat                       | 0.003000 | 1.000 | 0.100 |
| 3500341001 35  | Sheep, fat-babyfood              | 0.003000 | 1.000 | 0.100 |
| 3500342000 35  | Sheep, kidney                    | 0.004500 | 1.000 | 0.100 |
| 3500343000 35  | Sheep, liver                     | 0.010000 | 1.000 | 0.100 |
| 3600222000 36  | Milk, fat                        | 0.002000 | 1.000 | 0.100 |
| 3600222001 36  | Milk, fat-baby food/infant formu | 0.002000 | 1.000 | 0.100 |
| 3600223000 36  | Milk, nonfat solids              | 0.000300 | 1.000 | 0.100 |
| 3600223001 36  | Milk, nonfat solids-baby food/in | 0.000300 | 1.000 | 0.100 |
| 3600224000 36  | Milk, water                      | 0.000300 | 1.000 | 0.100 |
| 3600224001 36  | Milk, water-babyfood/infant form | 0.000300 | 1.000 | 0.100 |
| 3600225001 36  | Milk, sugar (lactose)-baby food/ | 0.000300 | 1.000 | 0.100 |
| 8601000000 86A | Water, direct, all sources       | 0.000150 | 1.000 | 1.000 |
| 8602000000 86B | Water, indirect, all sources     | 0.000150 | 1.000 | 1.000 |

# Attachment 6: Chronic Results File

U.S. EPA Ver. 3.16, 03-08-d  
DEEM-FCID Chronic analysis for EMAMECTIN BENZOATE NHANES 2001-2008 2 day  
Residue file name: C:\Documents and Settings\NDODD\My Documents\DEEM Version  
1.16\emamectin benzoate 2013\EMAMECTINCHRONICCURBITS 121212.R08  
Adjustment factor #2 used.  
Analysis Date 12-19-2012/12:54:01 Residue file dated: 12-19-2012/12:52:17  
Reference dose (RfD, Chronic) = .000075 mg/kg bw/day  
COMMENT 1: General Population; include pome fruits + drinking water:  
-----  
Total exposure by population subgroup  
-----

| Population Subgroup | Total Exposure    |                |
|---------------------|-------------------|----------------|
|                     | mg/kg body wt/day | Percent of RfD |
| Total US Population | 0.000006          | 7.5%           |
| Hispanic            | 0.000005          | 7.0%           |
| Non-Hisp White      | 0.000006          | 7.5%           |
| Non-Hisp Black      | 0.000006          | 7.7%           |
| Non-Hisp Other      | 0.000007          | 9.2%           |
| Nursing Infants     | 0.000006          | 7.5%           |
| Non-Nursing Infants | 0.000014          | 19.0%          |
| Female 13+ PREG     | 0.000005          | 6.9%           |
| Children 1-6        | 0.000009          | 12.6%          |
| Children 7-12       | 0.000005          | 7.0%           |
| Male 13-19          | 0.000004          | 5.1%           |
| Female 13-19/NP     | 0.000004          | 5.2%           |
| Male 20+            | 0.000005          | 6.8%           |
| Female 20+/NP       | 0.000006          | 7.6%           |
| Seniors 55+         | 0.000006          | 7.5%           |
| All Infants         | 0.000012          | 15.5%          |
| Female 13-50        | 0.000005          | 6.8%           |
| Children 1-2        | 0.000011          | 15.3%          |
| Children 3-5        | 0.000009          | 11.5%          |
| Children 6-12       | 0.000006          | 7.4%           |
| Youth 13-19         | 0.000004          | 5.2%           |
| Adults 20-49        | 0.000005          | 6.9%           |
| Adults 50-99        | 0.000006          | 7.7%           |
| Female 13-49        | 0.000005          | 6.8%           |





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON D.C., 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

PC Code: 122806  
DP Barcodes: DP 402307

May 30, 2012

MEMORANDUM

SUBJECT: Amended Drinking Water Assessment for the proposed use of Emamectin Benzoate on outdoor ornamentals and Group 9 cucurbit vegetables.

TO: Barbara Madden, Risk Manager  
Andrew Ertman, Reviewer  
Registration Division (7505P)

Venus Eagle, Risk Manager  
Thomas Harris, Reviewer  
Registration Division (7505P)

FROM: Tiffany Downen, Environmental Engineer *Tiffany Downen* 5/30/12  
James Hetrick, Ph.D., Senior Science Advisor *James C. Hetrick* 5/30/12  
Rosanna Louie-Juzwiak, RAPL *Rosanna Louie-Juzwiak* 5/30/2012  
Dana Spatz, Branch Chief *Dana Spatz* 5/30/12  
Environmental Risk Branch 3  
Environmental Fate and Effects Division (7507P)

The Environmental Fate and Effects Division [EFED] has been requested to provide a drinking water assessment (DWA) for the proposed uses of emamectin benzoate on outdoor ornamentals (EPA 100-RURR) and Group 9 Cucurbit Vegetables (EPA 100-904). The rates for the proposed use from labels 100-RURR and 100-904 were compared with the rates of previously registered uses (Table 1). The highest estimated drinking water concentration (EDWCs) result from the proposed application to outdoor-grown ornamentals, and is the drinking water exposure driver. These EDWCs also incorporate three new aerobic soil metabolism studies (MRID 48480101, 48480102, 48480103). Emamectin benzoate residues (parent+degradation products), based on applications made to ornamentals and group 9 cucurbits, are not expected to exceed 0.465 µg/L

for the 1 in 10 year daily peak, 0.150 µg/L for the 1 in 10 year annual average, and 0.112 µg/L for the 30 year annual average (see Table 2). For details on the studies, please see their respective data evaluation reviews (DERs) completed 1/6/2012 (MRIDs 48480101, 48480102) and 1/11/12 (MRID 48480103).

| <b>Table 1: Comparison of the Proposed Use of Emamectin Benzoate on Outdoor Ornamentals and Group 9 Cucurbit Vegetables to Previous DWA on Pistachios and Tree Nuts (January 31, 2008, DP 347918)</b> |                                        |                                       |                                              |                                          |                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|---------------------------------------|----------------------------------------------|------------------------------------------|---------------------|
| <b>Use Label (DP Barcode)</b>                                                                                                                                                                         | <b>Maximum Single application rate</b> | <b>Maximum Number of Applications</b> | <b>Minimum Interval between Applications</b> | <b>Seasonal Maximum Application Rate</b> | <b>Percent a.i.</b> |
| <i>Outdoor Ornamentals</i><br>100-RURR<br>(396195)<br>And<br><i>Group 9 Cucurbits</i><br>100-904<br>(392511)                                                                                          | 0.015 lb a.i./A                        | 6                                     | 7 days                                       | 0.094 lb a.i./A                          | 5%                  |
| <i>*Pistachios and Tree Nuts Proclaim™</i><br>(347918)                                                                                                                                                | 0.015 lb a.i./A                        | 3                                     | 7 days                                       | 0.045 lb a.i./A                          | 5%                  |

\* The maximum and yearly application rates for the previous pistachio and tree nut drinking water assessment (January 31, 2008, DP 347918), were revised. The values represented in the table above are representative of current label values for maximum and yearly application rates. Since the proposed new uses have higher rates than the revised pistachio and tree nut rates, this assessment will focus on the new use rates which are expected to provide the most conservative EDWCs. This new amended DWA overrides the previous DWA on this use (DP 396195, DP 392511).

With the incorporation of the recently submitted fate studies, the PRZM/EXAMS EDWCs, based on use rates for emamectin benzoate residues (parent+degradation products) are not expected to exceed 0.465 µg/L for the 1 in 10 year daily peak, 0.150 µg/L for the 1 in 10 year annual average, and 0.112 µg/L for the 30 year annual average (see Table 2). These EDWCs are recommended by EFED for use by HED in their dietary risk assessment. Appendix 1 contains the modeling outputs with the newly calculated aerobic soil metabolism and aerobic aquatic half-lives.

| Table 2: EDWCs for Emamectin Benzoate Residues from Use on Outdoor Ornamentals |                         |              |             |                        |
|--------------------------------------------------------------------------------|-------------------------|--------------|-------------|------------------------|
| Use                                                                            | Model                   | 1 in 10 year |             | 30 year Annual Average |
|                                                                                |                         | Peak         | Annual Mean |                        |
|                                                                                |                         | µg/L         |             |                        |
| Surface Water                                                                  |                         |              |             |                        |
| Ornamental                                                                     | PRZM/EXAMS <sup>1</sup> | 0.465        | 0.160       | 0.112                  |
| Ground Water                                                                   |                         |              |             |                        |
| Ornamental/ Group 9 Cucurbit Vegetables                                        | SCI-GROW                | 0.54         | 0.54        | 0.54                   |

<sup>1</sup>Degradates of concern included in the calculation of EDWCs: (8,9-Z)-4"-epimethylamino-4"-deoxy anermectin B1, 4"-epiamino-4"-deoxyavermectin B1, anermectin B1 monosaccharide, and 4"-epi-(N-formyl)-4"-deoxyavermectin B1 (the 8,9 ZMA isomer, AB, MAB, and FAB, respectively).

<sup>1</sup> Typically, the values generated by the models for drinking water are multiplied by a percent crop area factor (PCA). The PCA accounts for the fact that it is unlikely for any basin to be completely planted to agricultural crops. The PCA adjustment factor is assumed to be 0.87<sup>1</sup> for the group 9 cucurbit vegetables and 1.0 for the outdoor ornamentals crops as per the PCA guidance.

### Modeling Inputs for Drinking Water Assessment:

PRZM (ver. 3.12.2)/ EXAMS (ver. 2.98.04.06), and SCI-GROW (ver. 2.3) models were used to estimate concentrations in drinking water for emamectin benzoate. The Agency identified four degradates of concern based on structural similarity to emamectin benzoate that are formed via photolysis (MARC memo references: D238206, Sept 2, 1997; D255357, Aug 20, 2001; D277085, Aug 20, 2001):

- (8,9-Z)-4"-epimethylamino-4"-deoxy avermectin B1 (8,9 ZMA isomer);
- 4"-epiamino-4"-deoxyavermectin B1 (AB);
- avermectin B1 monosaccharide (MAB); and
- 4"-epi-(N-formyl)-4"-deoxyavermectin B1 (FAB)

These degradates were included in the drinking water assessment for emamectin benzoate and are assumed to be of equal or lesser toxicity to that of the parent compound. The total toxic residues approach is used for determining the environmental fate data parameters for modeling using the *Guidance for Selecting Input Parameters in Modeling the Environmental Fate and Transport of Pesticides*, Version 2.1, October 22, 2009, and the draft *Guidance for Modeling Pesticides Total Toxic Residues (TTR)*, dated May 20, 2009. Please see **Table 3** below with a list of the input parameters used in the surface and ground water assessments. The previous half-life values and sources are shown in *italics* in order to show where the changes that were made.

**Table 3: Model Input Parameters for Combined Residues of Emamectin Benzoate.**

| Parameters*                                                          | Values & Units                                        | Sources                                                                                                                                                                                     |
|----------------------------------------------------------------------|-------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Molecular Weight                                                     | 964.23                                                | Science Chapter (New Chemical Review, D226628)                                                                                                                                              |
| Henry's Law Constant (25°C)                                          | $3.8 \times 10^{-10}$ atm m <sup>3</sup> /mol         | Product Chemistry: MRID 44883705                                                                                                                                                            |
| Aqueous Solubility (pH 7.0 and 25°C)                                 | 93 ppm                                                | Product Chemistry: MRID 44883704                                                                                                                                                            |
| Hydrolysis Half-Life (pH7)                                           | Stable                                                | MRID 42743642                                                                                                                                                                               |
| Aerobic Soil Metabolism Half-Life                                    | 90 <sup>th</sup> percentile on the mean: 107.5 days** | MRID 43404303 (193.4), 48480101 (75.3, 78.8), 48480102 (60.8, 35.9), 48480103 (57.8, 50.2) . Per input Parameter Guidance. ( <i>MRID 43404303: 193 times 3 for single value= 579 days</i> ) |
| Anaerobic Aquatic Metabolism Half-Life (total sediment/water system) | 1,281 days                                            | MRID 43580116: 427 times 3 for single value                                                                                                                                                 |
| Aerobic Aquatic Metabolism Half-Life (total sediment/water system)   | 215 days**                                            | aerobic half-life value: 107.5 times 2 per Input Parameter Guidance. ( <i>193 times 3 times 2 for single value= 1,158 days</i> )                                                            |
| Aqueous Photolysis Half-Life                                         | 23 days                                               | MRID 43850114; maximum value                                                                                                                                                                |
| Soil Water Partition Coefficient                                     | 265,687                                               | MRID 428515-26; K <sub>oc</sub> = 279,000 - 730,000 - 25,382 - 28,365)                                                                                                                      |
| Pesticide Wetted-In                                                  | No                                                    | Product Label                                                                                                                                                                               |

<sup>1</sup> Guidance on Development and Use of Percent Cropped Area Adjustment Factors in Drinking Water Exposure Assessments September 9, 2010



| Crop Management – CAnurserySTD for Outdoor Ornamentals |                     |                    |
|--------------------------------------------------------|---------------------|--------------------|
| Application Rate                                       | 0.015 lb. a.i./acre | Product Label      |
| Number of Applications                                 | 6                   | Product Label      |
| Application Interval                                   | 7 days              | Product Label      |
| First Application Date                                 | April 1             | Product Label      |
| Application Method                                     | aerial              | Product Label      |
| Spray Efficiency                                       | 0.95                | EFED default value |
| Spray Drift (Index Res. Scenario)                      | 0.16                | EFED default value |

\*As appropriate, half-lives were adjusted when the following degradates of concern were present: (8,9-Z)-4"-epimethylamino-4"-deoxy anermectin B1, 4"-epiamino-4"-deoxyavermectin B1, anermectin B1 monosaccharide, and 4"-epi-(N-formyl)-4"-deoxyavermectin B1 (the 8,9 ZMA isomer, AB, MAB, and FAB, respectively).

\*\*The aerobic soil metabolism half-life used in SCI-GROW is the mean of all of the values (79 days).

### Monitoring Data:

The California Department of Pesticide Regulation (CDPR) surface water database (<http://www.cdpr.ca.gov/docs/emon/surfwtr/surfcont.htm>), USGS NAWQA surface and ground water database (<http://infotrek.er.usgs.gov/apex/f?p=136:1:0::NO::>), Pesticide Data Program (<http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateG&navID=&rightNav1=&topNav=&leftNav=ScienceandLaboratories&page=PDPDownloadData/Reports&resultType=&acct=pestcddataprg>), and the USGS/EPA Reservoir Data Program were evaluated for available monitoring data. No detects were seen for emamectin or avermectin at any of these databases.

## CITATIONS

- Burns, L. A. 2002. EXAMS (Exposure Analysis Modeling System) Version 2.98.04.06. Environmental Research Laboratory. U. S. Environmental Protection Agency. Athens, GA.
- Carsel et al., 1997. PRZM (Pesticide Root Zone Model) Version 3.12.2 Environmental Research Laboratory. U. S. Environmental Protection Agency. Athens, GA.
- Jones, R.D. et al., 2000. Guidance for use of the Index Reservoir and Percent Crop Area Factor in Drinking Water Assessments (March 21, 2000). Office of Pesticide Programs, Environmental Fate and Effects Division, U.S. Environmental Protection Agency. Arlington, VA.
- SCI-GROW (Screening Concentration In Ground Water) 2003. (Version 2.3; July 29, 2003). Environmental Fate and Effects Division, Office of Pesticide Programs, U.S. Environmental Protection Agency, Arlington, VA.  
<http://www.epa.gov/oppefed1/models/water/index.htm>
- USEPA, 2009a. Guidance for Selecting Input Parameters in Modeling the Environmental Fate and Transport of Pesticides. Version 2.1 October 22, 2009.  
[http://www.epa.gov/oppefed1/models/water/input\\_guidance2\\_28\\_02.htm](http://www.epa.gov/oppefed1/models/water/input_guidance2_28_02.htm). U.S. Environmental Protection Agency, Office of Pesticide Programs, Environmental Fate and Effects Division. Arlington, VA.
- USEPA, 2009b. DRAFT Guidance for Modeling Pesticides Total Toxic Residues (TTR) May 20, 2009. U.S. Environmental Protection Agency, Office of Pesticide Programs, Environmental Fate and Effects Division. Arlington, VA.
- U.S. EPA. 2003. Use of Regional Percent Crop Area Factors in Refined Drinking Water Assessments. US EPA Office of Pesticide Programs (OPP), Environmental Fate and Effects Division (EFED), Water Quality Technical Team (WQTT). Arlington, VA.
- USEPA 2010. Guidance on Development and Use of Percent Cropped Area Adjustment Factors in Drinking Water Exposure Assessments September 9, 2010. U.S. Environmental Protection Agency, Office of Pesticide Programs, Environmental Fate and Effects Division. Arlington, VA.  
[http://www.epa.gov/oppefed1/models/water/index\\_reservoir\\_dwa.html](http://www.epa.gov/oppefed1/models/water/index_reservoir_dwa.html)

## APPENDIX 1. Model Outputs and Comparisons

### PRZM/EXAMS Surface Water Estimates Ornamentals and Group 9 Cucurbits

| Crop or Crop Group                          | Maximum Application Rate | Total (season or crop) | Minimum Application Interval | Scenario (State crop) Scenario | 1 <sup>st</sup> Application date (mn-day) | Application Method | EDWCs (µg/L) |                             |                        |
|---------------------------------------------|--------------------------|------------------------|------------------------------|--------------------------------|-------------------------------------------|--------------------|--------------|-----------------------------|------------------------|
|                                             |                          |                        |                              |                                |                                           |                    | Peak         | 1 in 10 year annual average | 30 year annual average |
| <i>Outdoor Ornamentals</i>                  | 0.015                    | 6                      | 7                            | CAnurserySTD                   | 1-Apr                                     | Aerial             | <b>0.465</b> | <b>0.150</b>                | <b>0.112</b>           |
|                                             |                          |                        |                              | FLnurserySTD                   | 2-Jan                                     |                    | 0.199        | 0.087                       | 0.073                  |
|                                             |                          |                        |                              | MinurserySTD                   | 2-Jan                                     |                    | 0.211        | 0.146                       | 0.102                  |
|                                             |                          |                        |                              | NJnurserySTD                   | 2-Jan                                     |                    | 0.261        | 0.152                       | 0.116                  |
|                                             |                          |                        |                              | ORnurserySTD                   | 2-Jan                                     |                    | 0.144        | 0.081                       | 0.060                  |
|                                             |                          |                        |                              | TNnurserySTD                   | 15-Apr                                    |                    | 0.356        | 0.165                       | 0.127                  |
| <i>Group 9 Cucurbits</i>                    | 0.015                    | 6                      | 7                            | FLcucumberSTD                  | 5-Dec***                                  | Aerial             | <i>0.137</i> | <i>0.065</i>                | <i>0.051</i>           |
| <i>Pistachios<sup>1</sup> and Tree Nuts</i> | 0.015                    | 3                      | 7                            | CAAlmondSTD                    | 8-Feb                                     | Airblast           | 0.037        | 0.015                       | 0.012                  |
|                                             |                          |                        |                              | GApecanSTD                     | 16-May                                    |                    | 0.284        | 0.059                       | 0.048                  |
|                                             |                          |                        |                              | ORFilbertsSTD                  | 1-Apr                                     |                    | <i>0.044</i> | <i>0.022</i>                | <i>0.017</i>           |
| <i>Pome Fruit<sup>2</sup></i>               | 0.015                    | 3                      | 7                            | ORApple                        | 1-Jun                                     | Aerial             | 0.095        | 0.042                       | 0.031                  |
|                                             |                          |                        |                              | PAApple                        | 25-May                                    |                    | 0.213        | 0.082                       | 0.061                  |
|                                             |                          |                        |                              | NCApple                        | 15-May                                    |                    | <i>0.241</i> | <i>0.081</i>                | <i>0.061</i>           |

\*Values in bold are the most conservative values. \*\*Application method for this label includes ground, airblast, and aerial. To be conservative, the aerial application method was evaluated.

\*\*\* The date of the first application for the Florida cucurbit scenario for foliar application suggests a start date of December 5<sup>th</sup>. However, since there are 6 applications with 7 day intervals, that pushes the 6<sup>th</sup> application into the next calendar year. Currently, PRZM/EXAMS cannot handle calculating applications going from one calendar year to the next. To attempt to determine the EDWCs for that time period (since weather data is based on the time of application as well as location etc.), the first application was made in January, and the remaining applications took place in December.

<sup>1</sup>: Please see the original assessment (DP 347918) for the detailed assessment on Pistachios and Tree Nuts. These numbers include revisions that incorporate the new data and a correction to the application rate, and are an amendment to the previously calculated EDWCs. A PCA of 0.87 was used for this use.

<sup>2</sup>: Please see the original assessment (DP 309157) for the detailed assessment on Pome Fruit. These numbers are revisions that incorporate the new data, and are an amendment to the previously calculated EDWCs. A PCA of 0.87 was used for this use.

### Example of output data for the CAnurserySTD and the FLcucumbersTD

stored as CAnursery.out

Chemical: emamectin benzoate

PRZM environment: CAnurserySTD\_V2.txt modified Tuesday, 27 May 2008 at 11:16:22

EXAMS environment: ir298.exv modified Tuesday, 26 August 2008 at 06:14:08

Metfile: w23188.dvf modified Tuesday, 26 August 2008 at 06:15:38

Water segment concentrations (ppb)

| Year | Peak    | 96 hr   | 21 Day  | 60 Day  | 90 Day  | Yearly   |
|------|---------|---------|---------|---------|---------|----------|
| 1961 | 0.09071 | 0.04127 | 0.02009 | 0.01484 | 0.01197 | 0.006687 |
| 1962 | 0.1388  | 0.0819  | 0.03736 | 0.03212 | 0.02917 | 0.02341  |
| 1963 | 0.1402  | 0.0742  | 0.0419  | 0.03666 | 0.03367 | 0.02877  |
| 1964 | 0.0973  | 0.06062 | 0.05056 | 0.04534 | 0.04232 | 0.03613  |
| 1965 | 0.3593  | 0.2048  | 0.1081  | 0.08083 | 0.06919 | 0.05222  |
| 1966 | 0.3735  | 0.2155  | 0.1116  | 0.08705 | 0.08422 | 0.07496  |
| 1967 | 0.2846  | 0.1786  | 0.1103  | 0.09831 | 0.09501 | 0.08994  |
| 1968 | 0.1563  | 0.1196  | 0.1096  | 0.1044  | 0.1011  | 0.09323  |
| 1969 | 0.4221  | 0.2263  | 0.1296  | 0.1148  | 0.1116  | 0.1046   |
| 1970 | 0.287   | 0.1769  | 0.1227  | 0.1146  | 0.1127  | 0.1053   |
| 1971 | 0.2013  | 0.1528  | 0.128   | 0.1223  | 0.1187  | 0.1118   |
| 1972 | 0.2798  | 0.1903  | 0.1326  | 0.1207  | 0.1173  | 0.1118   |
| 1973 | 0.176   | 0.1393  | 0.1294  | 0.1242  | 0.1207  | 0.1129   |
| 1974 | 0.3145  | 0.1944  | 0.1324  | 0.126   | 0.1226  | 0.1171   |
| 1975 | 0.2508  | 0.1708  | 0.1427  | 0.1355  | 0.1329  | 0.1218   |
| 1976 | 0.3529  | 0.2313  | 0.1517  | 0.1387  | 0.1381  | 0.1267   |



|      |        |        |        |        |        |        |
|------|--------|--------|--------|--------|--------|--------|
| 1977 | 0.9049 | 0.4493 | 0.2156 | 0.1733 | 0.165  | 0.1454 |
| 1978 | 0.3065 | 0.207  | 0.1599 | 0.1547 | 0.151  | 0.1435 |
| 1979 | 0.266  | 0.1937 | 0.1627 | 0.1576 | 0.1538 | 0.1456 |
| 1980 | 0.3666 | 0.2345 | 0.1679 | 0.162  | 0.1595 | 0.1502 |
| 1981 | 0.4063 | 0.246  | 0.1632 | 0.1538 | 0.1519 | 0.1428 |
| 1982 | 0.265  | 0.1903 | 0.1626 | 0.1607 | 0.1563 | 0.1459 |
| 1983 | 0.226  | 0.182  | 0.1642 | 0.159  | 0.1567 | 0.1462 |
| 1984 | 0.3098 | 0.2043 | 0.1551 | 0.145  | 0.1413 | 0.1344 |
| 1985 | 0.4696 | 0.2738 | 0.186  | 0.1575 | 0.1476 | 0.1384 |
| 1986 | 0.344  | 0.226  | 0.1668 | 0.158  | 0.1542 | 0.1491 |
| 1987 | 0.282  | 0.2    | 0.1647 | 0.1602 | 0.1563 | 0.15   |
| 1988 | 0.4717 | 0.3198 | 0.2095 | 0.1807 | 0.1747 | 0.1595 |
| 1989 | 0.2151 | 0.1783 | 0.1685 | 0.1633 | 0.1597 | 0.1511 |
| 1990 | 0.2071 | 0.1703 | 0.1605 | 0.1553 | 0.1519 | 0.1432 |

#### Sorted results

| Prob.              | Peak    | 96 hr   | 21 Day  | 60 Day  | 90 Day  | Yearly   |  |
|--------------------|---------|---------|---------|---------|---------|----------|--|
| 0.032258064516129  | 0.9049  | 0.4493  | 0.2156  | 0.1807  | 0.1747  | 0.1595   |  |
| 0.0645161290322581 | 0.4717  | 0.3198  | 0.2095  | 0.1733  | 0.165   | 0.1511   |  |
| 0.0967741935483871 | 0.4696  | 0.2738  | 0.186   | 0.1633  | 0.1597  | 0.1502   |  |
| 0.129032258064516  | 0.4221  | 0.246   | 0.1685  | 0.162   | 0.1595  | 0.15     |  |
| 0.161290322580645  | 0.4063  | 0.2345  | 0.1679  | 0.1607  | 0.1567  | 0.1491   |  |
| 0.193548387096774  | 0.3735  | 0.2313  | 0.1668  | 0.1602  | 0.1563  | 0.1462   |  |
| 0.225806451612903  | 0.3666  | 0.2263  | 0.1647  | 0.159   | 0.1563  | 0.1459   |  |
| 0.258064516129032  | 0.3593  | 0.226   | 0.1642  | 0.158   | 0.1542  | 0.1456   |  |
| 0.290322580645161  | 0.3529  | 0.2155  | 0.1632  | 0.1576  | 0.1538  | 0.1454   |  |
| 0.32258064516129   | 0.344   | 0.207   | 0.1627  | 0.1575  | 0.1519  | 0.1435   |  |
| 0.354838709677419  | 0.3145  | 0.2048  | 0.1626  | 0.1553  | 0.1519  | 0.1432   |  |
| 0.387096774193548  | 0.3098  | 0.2043  | 0.1605  | 0.1547  | 0.151   | 0.1428   |  |
| 0.419354838709677  | 0.3065  | 0.2     | 0.1599  | 0.1538  | 0.1476  | 0.1384   |  |
| 0.451612903225806  | 0.287   | 0.1944  | 0.1551  | 0.145   | 0.1413  | 0.1344   |  |
| 0.483870967741936  | 0.2846  | 0.1937  | 0.1517  | 0.1387  | 0.1381  | 0.1267   |  |
| 0.516129032258065  | 0.282   | 0.1903  | 0.1427  | 0.1355  | 0.1329  | 0.1218   |  |
| 0.548387096774194  | 0.2798  | 0.1903  | 0.1326  | 0.126   | 0.1226  | 0.1171   |  |
| 0.580645161290323  | 0.266   | 0.182   | 0.1324  | 0.1242  | 0.1207  | 0.1129   |  |
| 0.612903225806452  | 0.265   | 0.1786  | 0.1296  | 0.1223  | 0.1187  | 0.1118   |  |
| 0.645161290322581  | 0.2508  | 0.1783  | 0.1294  | 0.1207  | 0.1173  | 0.1118   |  |
| 0.67741935483871   | 0.226   | 0.1769  | 0.128   | 0.1148  | 0.1127  | 0.1053   |  |
| 0.709677419354839  | 0.2151  | 0.1708  | 0.1227  | 0.1146  | 0.1116  | 0.1046   |  |
| 0.741935483870968  | 0.2071  | 0.1703  | 0.1116  | 0.1044  | 0.1011  | 0.09323  |  |
| 0.774193548387097  | 0.2013  | 0.1528  | 0.1103  | 0.09831 | 0.09501 | 0.08994  |  |
| 0.806451612903226  | 0.176   | 0.1393  | 0.1096  | 0.08705 | 0.08422 | 0.07496  |  |
| 0.838709677419355  | 0.1563  | 0.1196  | 0.1081  | 0.08083 | 0.06919 | 0.05222  |  |
| 0.870967741935484  | 0.1402  | 0.0819  | 0.05056 | 0.04534 | 0.04232 | 0.03613  |  |
| 0.903225806451613  | 0.1388  | 0.0742  | 0.0419  | 0.03666 | 0.03367 | 0.02877  |  |
| 0.935483870967742  | 0.0973  | 0.06062 | 0.03736 | 0.03212 | 0.02917 | 0.02341  |  |
| 0.967741935483871  | 0.09071 | 0.04127 | 0.02009 | 0.01484 | 0.01197 | 0.006687 |  |

0.1 0.46485 0.27102 0.18425 0.16317 0.15968 0.15018

Average of yearly averages: 0.112088233333333

Inputs generated by pe5.pl - November 2006

Data used for this run:

Output File: CANursery

Metfile: w23188.dvf

PRZM scenario: CANurserySTD\_V2.txt

EXAMS environment file: ir298.exv

Chemical Name: emamectin benzoate

| Description                  | Variable Name | Value   | Units                   | Comments  |
|------------------------------|---------------|---------|-------------------------|-----------|
| Molecular weight             | mwt           | 964.23  | g/mol                   |           |
| Henry's Law Const.           | henry         | 3.8e-10 | atm-m <sup>3</sup> /mol |           |
| Vapor Pressure               | vapr          |         | torr                    |           |
| Solubility sol               | 930           | mg/L    |                         |           |
| Kd                           | Kd            | mg/L    |                         |           |
| Koc                          | Koc           | 265687  | mg/L                    |           |
| Photolysis half-life         | kdp           | 23      | days                    | Half-life |
| Aerobic Aquatic Metabolism   | kbacw         | 215     | days                    | Halfife   |
| Anaerobic Aquatic Metabolism | kbacs         | 1281    | days                    | Halfife   |
| Aerobic Soil Metabolism      | asm           | 107.5   | days                    | Halfife   |

Hydrolysis: pH 5 0 days Half-life  
Hydrolysis: pH 7 0 days Half-life  
Hydrolysis: pH 9 0 days Half-life  
Method: CAM 2 integer See PRZM manual  
Incorporation Depth: DEPI 0 cm  
Application Rate: TAPP 0.017 kg/ha  
Application Efficiency: APPEFF 0.95 fraction  
Spray Drift: DRFT 0.16 fraction of application rate applied to pond  
Application Date: Date 1-4 dd/mm or dd/mm or dd-mm or dd-mmm  
Interval 1 interval 7 days Set to 0 or delete line for single app.  
app. rate 1 apprate 0.017 kg/ha  
Interval 2 interval 7 days Set to 0 or delete line for single app.  
app. rate 2 apprate 0.017 kg/ha  
Interval 3 interval 7 days Set to 0 or delete line for single app.  
app. rate 3 apprate 0.017 kg/ha  
Interval 4 interval 7 days Set to 0 or delete line for single app.  
app. rate 4 apprate 0.017 kg/ha  
Interval 5 interval 7 days Set to 0 or delete line for single app.  
app. rate 5 apprate 0.017 kg/ha  
Record 17: FILTRA  
IPSCND 1  
UPTKF  
Record 18: PLVKRT  
PLDKRT  
FEXTRC 0.5  
Flag for Index Res. Run IR Reservoir  
Flag for runoff calc. RUNOFF total none, monthly or total(average of entire run)

stored as FLCucumber.out

Chemical: emamectin benzoate

PRZM environment: FLCucumberSTD.txt modified Tuesday, 26 August 2008 at 06:16:38

EXAMS environment: ir298.exv modified Tuesday, 26 August 2008 at 06:14:08

Metfile: w12844.dvf modified Tuesday, 26 August 2008 at 06:14:22

Water segment concentrations (ppb)

| Year | Peak    | 96 hr   | 21 Day  | 60 Day  | 90 Day   | Yearly   |
|------|---------|---------|---------|---------|----------|----------|
| 1961 | 0.06718 | 0.03051 | 0.02026 | 0.01175 | 0.008321 | 0.003434 |
| 1962 | 0.07737 | 0.04    | 0.02954 | 0.02085 | 0.01742  | 0.01211  |
| 1963 | 0.08426 | 0.04677 | 0.03902 | 0.02889 | 0.02556  | 0.01992  |
| 1964 | 0.09552 | 0.05769 | 0.04766 | 0.03938 | 0.03628  | 0.03122  |
| 1965 | 0.09924 | 0.0639  | 0.05266 | 0.04407 | 0.0412   | 0.03661  |
| 1966 | 0.1221  | 0.07754 | 0.06104 | 0.05282 | 0.04974  | 0.04654  |
| 1967 | 0.1102  | 0.07358 | 0.06341 | 0.05526 | 0.05237  | 0.04973  |
| 1968 | 0.1168  | 0.08007 | 0.06993 | 0.06177 | 0.05879  | 0.05493  |
| 1969 | 0.1409  | 0.09058 | 0.07363 | 0.06548 | 0.06247  | 0.06022  |
| 1970 | 0.1246  | 0.08786 | 0.07766 | 0.06961 | 0.06796  | 0.0658   |
| 1971 | 0.1245  | 0.08828 | 0.07634 | 0.06853 | 0.06519  | 0.06369  |
| 1972 | 0.1265  | 0.08941 | 0.07951 | 0.07147 | 0.0696   | 0.06652  |
| 1973 | 0.1259  | 0.08969 | 0.07736 | 0.0691  | 0.06716  | 0.06513  |
| 1974 | 0.1545  | 0.1071  | 0.08059 | 0.0721  | 0.07056  | 0.06609  |
| 1975 | 0.1243  | 0.088   | 0.07505 | 0.067   | 0.06441  | 0.06262  |
| 1976 | 0.1246  | 0.09483 | 0.07718 | 0.06909 | 0.066    | 0.06405  |
| 1977 | 0.1478  | 0.0976  | 0.08323 | 0.07326 | 0.06976  | 0.06741  |
| 1978 | 0.1307  | 0.09832 | 0.0828  | 0.07351 | 0.07059  | 0.06853  |
| 1979 | 0.1578  | 0.1036  | 0.082   | 0.07384 | 0.07086  | 0.06915  |
| 1980 | 0.129   | 0.09324 | 0.0822  | 0.07439 | 0.07316  | 0.07078  |
| 1981 | 0.1291  | 0.09286 | 0.08199 | 0.07301 | 0.07071  | 0.0684   |
| 1982 | 0.1671  | 0.1137  | 0.08512 | 0.07753 | 0.07713  | 0.07329  |
| 1983 | 0.1738  | 0.1181  | 0.09058 | 0.08315 | 0.08131  | 0.07734  |
| 1984 | 0.1364  | 0.09975 | 0.08944 | 0.08193 | 0.07966  | 0.0779   |
| 1985 | 0.1363  | 0.1001  | 0.08573 | 0.07772 | 0.07729  | 0.07483  |
| 1986 | 0.1492  | 0.1146  | 0.08931 | 0.07978 | 0.07855  | 0.07449  |
| 1987 | 0.1349  | 0.09805 | 0.08497 | 0.07724 | 0.07555  | 0.07359  |
| 1988 | 0.1327  | 0.09594 | 0.08556 | 0.07751 | 0.07508  | 0.07354  |
| 1989 | 0.1322  | 0.0959  | 0.08166 | 0.07335 | 0.0724   | 0.06959  |
| 1990 | 0.1291  | 0.09199 | 0.07854 | 0.07053 | 0.06804  | 0.06656  |

Sorted results

| Prob. | Peak | 96 hr | 21 Day | 60 Day | 90 Day | Yearly |
|-------|------|-------|--------|--------|--------|--------|
|-------|------|-------|--------|--------|--------|--------|

|                             |         |         |          |          |          |           |
|-----------------------------|---------|---------|----------|----------|----------|-----------|
| 0.032258064516129           | 0.1738  | 0.1181  | 0.09058  | 0.08315  | 0.08131  | 0.0779    |
| 0.0645161290322581          | 0.1671  | 0.1146  | 0.08944  | 0.08193  | 0.07966  | 0.07734   |
| 0.0967741935483871          | 0.1578  | 0.1137  | 0.08931  | 0.07978  | 0.07855  | 0.07483   |
| 0.129032258064516           | 0.1545  | 0.1071  | 0.08573  | 0.07772  | 0.07729  | 0.07449   |
| 0.161290322580645           | 0.1492  | 0.1036  | 0.08556  | 0.07753  | 0.07713  | 0.07359   |
| 0.193548387096774           | 0.1478  | 0.1001  | 0.08512  | 0.07751  | 0.07555  | 0.07354   |
| 0.225806451612903           | 0.1409  | 0.09975 | 0.08497  | 0.07724  | 0.07508  | 0.07329   |
| 0.258064516129032           | 0.1364  | 0.09832 | 0.08323  | 0.07439  | 0.07316  | 0.07078   |
| 0.290322580645161           | 0.1363  | 0.09805 | 0.0828   | 0.07384  | 0.0724   | 0.06959   |
| 0.32258064516129            | 0.1349  | 0.0976  | 0.0822   | 0.07351  | 0.07086  | 0.06915   |
| 0.354838709677419           | 0.1327  | 0.09594 | 0.082    | 0.07335  | 0.07071  | 0.06853   |
| 0.387096774193548           | 0.1322  | 0.0959  | 0.08199  | 0.07326  | 0.07059  | 0.0684    |
| 0.419354838709677           | 0.1307  | 0.09483 | 0.08166  | 0.07301  | 0.07056  | 0.06741   |
| 0.451612903225806           | 0.1291  | 0.09324 | 0.08059  | 0.0721   | 0.06976  | 0.06656   |
| 0.483870967741936           | 0.1291  | 0.09286 | 0.07951  | 0.07147  | 0.0696   | 0.06652   |
| 0.516129032258065           | 0.129   | 0.09199 | 0.07854  | 0.07053  | 0.06804  | 0.06609   |
| 0.548387096774194           | 0.1265  | 0.09058 | 0.07766  | 0.06961  | 0.06796  | 0.0658    |
| 0.580645161290323           | 0.1259  | 0.08969 | 0.07736  | 0.0691   | 0.06716  | 0.06513   |
| 0.612903225806452           | 0.1246  | 0.08941 | 0.07718  | 0.06909  | 0.066    | 0.06405   |
| 0.645161290322581           | 0.1246  | 0.08828 | 0.07634  | 0.06853  | 0.06519  | 0.06369   |
| 0.67741935483871            | 0.1245  | 0.088   | 0.07505  | 0.067    | 0.06441  | 0.06262   |
| 0.709677419354839           | 0.1243  | 0.08786 | 0.07363  | 0.06548  | 0.06247  | 0.06022   |
| 0.741935483870968           | 0.1221  | 0.08007 | 0.06993  | 0.06177  | 0.05879  | 0.05493   |
| 0.774193548387097           | 0.1168  | 0.07754 | 0.06341  | 0.05526  | 0.05237  | 0.04973   |
| 0.806451612903226           | 0.1102  | 0.07358 | 0.06104  | 0.05282  | 0.04974  | 0.04654   |
| 0.838709677419355           | 0.09924 | 0.0639  | 0.05266  | 0.04407  | 0.0412   | 0.03661   |
| 0.870967741935484           | 0.09552 | 0.05769 | 0.04766  | 0.03938  | 0.03628  | 0.03122   |
| 0.903225806451613           | 0.08426 | 0.04677 | 0.03902  | 0.02889  | 0.02556  | 0.01992   |
| 0.935483870967742           | 0.07737 | 0.04    | 0.02954  | 0.02085  | 0.01742  | 0.01211   |
| 0.967741935483871           | 0.06718 | 0.03051 | 0.02026  | 0.01175  | 0.008321 | 0.003434  |
| 0.1                         | 0.15747 | 0.11304 | 0.088952 | 0.079574 | 0.078424 | 0.074796  |
| Average of yearly averages: |         |         |          |          |          | 0.0591338 |

Inputs generated by pe5.pl - November 2006

Data used for this run:

Output File: FLCucumber

Metfile: wl2844.dvf

PRZM scenario: FLCucumberSTD.txt

EXAMS environment file: ir298.exv

Chemical Name: emamectin benzoate

| Description                  | Variable Name | Value   | Units                                        | Comments        |
|------------------------------|---------------|---------|----------------------------------------------|-----------------|
| Molecular weight             | mwt           | 964.23  | g/mol                                        |                 |
| Henry's Law Const.           | henry         | 3.8e-10 | atm-m <sup>3</sup> /mol                      |                 |
| Vapor Pressure               | vapr          |         | torr                                         |                 |
| Solubility                   | sol           | 93      | mg/L                                         |                 |
| Kd                           | Kd            |         | mg/L                                         |                 |
| Koc                          | Koc           | 265687  | mg/L                                         |                 |
| Photolysis half-life         | kdp           | 23      | days                                         | Half-life       |
| Aerobic Aquatic Metabolism   | kbacw         | 215     | days                                         | Halfife         |
| Anaerobic Aquatic Metabolism | kbacs         | 1281    | days                                         | Halfife         |
| Aerobic Soil Metabolism      | asm           | 107.5   | days                                         | Halfife         |
| Hydrolysis:                  | pH 5          | 0       | days                                         | Half-life       |
| Hydrolysis:                  | pH 7          | 0       | days                                         | Half-life       |
| Hydrolysis:                  | pH 9          | 0       | days                                         | Half-life       |
| Method:                      | CAM           | 2       | integer                                      | See PRZM manual |
| Incorporation Depth:         | DEPI          | 0       | cm                                           |                 |
| Application Rate:            | TAPP          | 0.017   | kg/ha                                        |                 |
| Application Efficiency:      | APPEFF        | 0.95    | fraction                                     |                 |
| Spray Drift                  | DRFT          | 0.16    | fraction of application rate applied to pond |                 |
| Application Date             | Date          | 5-1     | dd/mm or dd/mm or dd-mm or dd-mmm            |                 |
| Interval 1 interval          | 327           | days    | Set to 0 or delete line for single app.      |                 |
| app. rate 1 apprate          | 0.017         | kg/ha   |                                              |                 |
| Interval 2 interval          | 7             | days    | Set to 0 or delete line for single app.      |                 |
| app. rate 2 apprate          | 0.017         | kg/ha   |                                              |                 |
| Interval 3 interval          | 7             | days    | Set to 0 or delete line for single app.      |                 |
| app. rate 3 apprate          | 0.017         | kg/ha   |                                              |                 |
| Interval 4 interval          | 7             | days    | Set to 0 or delete line for single app.      |                 |
| app. rate 4 apprate          | 0.017         | kg/ha   |                                              |                 |



Interval 5 interval 7 days Set to 0 or delete line for single app.  
 app. rate 5 apprate 0.017 kg/ha  
 Record 17: FILTRA  
           IPSCND 1  
           UPTKF  
 Record 18: PLVKRT  
           PLDKRT  
           FEXTRC 0.5  
 Flag for Index Res. Run IR Reservoir  
 Flag for runoff calc. RUNOFF total none, monthly or total(average of entire run)

#### Sci-Grow Ground Water Estimates for Outdoor Ornamentals and Group 9 Cucurbits

Scigrow 2.3

output file scigrow\_output.txt

Emamectin Benzoate chemical name

0.015 application rate (lb/acre)

6 number of applications

265687 Koc (mL/g)

79 soil metabolism half-life (days)

run

Groundwater Concentration (ppb)

5.40E-04

input guidance

exit

#### Sci-Grow Ground Water Estimates for Pistachios, Tree Nuts, and Pome Fruits

Scigrow 2.3

output file scigrow\_output.txt

Emamectin Benzoate chemical name

0.015 application rate (lb/acre)

3 number of applications

265687 Koc (mL/g)

79 soil metabolism half-life (days)

run

Groundwater Concentration (ppb)

2.70E-04

input guidance

exit



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON D.C., 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

PC Code: 122806  
DP Barcodes: 390789  
Date: March 27, 2012

*See 100-904  
for DERs*

**MEMORANDUM**

**SUBJECT:** Environmental Fate and Effects Division Review of the Environmental Fate Data for Eamectin Benzoate.

**TO:** John Hebert, Risk Manager  
Thomas Harris, Reviewer  
Registration Division (7505P)

**THROUGH:** Dana Spatz, Branch Chief *[Signature]*  
Rosanna Louie-Juzwiak, Risk Assessment Process Leader *[Signature]*  
Environmental Risk Branch III  
Environmental Fate and Effects Division (7507P)

**FROM:** Tiffany Downen, Environmental Engineer *[Signature]*  
Environmental Risk Branch III  
Environmental Fate and Effects Division (7507P)

Please find attached the data evaluation records (DER) for the following studies evaluating the ecological fate (Table 1) of emamectin benzoate:

**Table 1. Ecological Fate Studies for Emamectin Benzoate.**

| GUIDE-LINE | MRID     | STUDY TITLE             | EPA CLASSIFICATION | COMMENTS                                                                                                                                                                                                                                                                                                                                                                         |
|------------|----------|-------------------------|--------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 835.4100   | 48480101 | Aerobic Soil Metabolism | Supplemental       | <p>This study is supplemental due to inconclusive formation and decline of transformation products.</p> <p>The study was terminated after only 100 days of incubation, at which time up to 37% of the applied remained. Although a half-life could be determined for the parent, the formation of some of the transformation products appeared to be at their maximum at the</p> |

| GUIDE-<br>LINE | MRID     | STUDY TITLE             | EPA<br>CLASSIFICATION | COMMENTS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|----------------|----------|-------------------------|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                |          |                         |                       | termination of the study (NOA-438309, NOA-415693). As a result, the decline and persistence of these degradates could not be determined. The minor transformation products NOA-415692, NOA-419150, and NOA-419153 were not conclusively identified or individually quantified. This can be used quantitatively for the parent compound, but does not meet guideline requirements.                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 835.4100       | 48480102 | Aerobic Soil Metabolism | Supplemental          | This study is supplemental for the Gartenacker and 18 acres soils. The kinetics for the Marsillagues soil are invalid due to the parent compound being present in excess of 76% at the termination of the study. This study provides useful information for the Gartenacker and 18 acres soils, but it is unknown if these soils are representative of U.S. soils. Likewise, multiple degradates in each of the soils were at their maximum or showing an increase in formation at termination of the study. As a result, the decline and persistence of these degradates could not be determined. These values determined for the Gartenacker and 18 acres soils can be used quantitatively, but do not meet the guideline requirements. The data from the Marsillagues soil cannot be used in risk assessments. |
| 835.4100       | 48480103 | Aerobic Soil Metabolism | Supplemental          | <p>This study is supplemental because a comparison to soils from the US was not provided. This study was performed on soil in Switzerland.</p> <p>The pesticide use history at the soil source site was not reported, and it was not confirmed that the soil was free of pesticide residues. This study does not meet</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |



| GUIDE-LINE | MRID | STUDY TITLE | EPA CLASSIFICATION | COMMENTS                                                                    |
|------------|------|-------------|--------------------|-----------------------------------------------------------------------------|
|            |      |             |                    | guideline requirements, but can be used quantitatively in risk assessments. |

The above studies were classified by EPA as supplemental. One study (MRID 48480102, was deemed supplemental, but one of the soil metabolism half-lives was invalidated due to the parent compound being present in excess of 76% at termination of the study with increasing formation of degradates. Therefore, the portion of the study referring to the Marsillagues soil cannot be used in risk assessment. The 'supplemental' studies deviated from guideline requirements for a variety of reasons (see Table 1). Some of the 'supplemental' studies are considered adequate for quantitative use in risk assessment, while others should not be used quantitatively in risk assessment, as indicated in the tables. If you have any questions regarding these data evaluation records, please do not hesitate to contact us.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON D.C., 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

PC Code: 122806  
Chemical: Enamectin Benzoate  
DP Barcodes: DP 392494, DP 396197

March 15, 2012

**MEMORANDUM**

**SUBJECT:** Ecological risk assessment for the new uses of Enamectin Benzoate on Group 9 cucurbit vegetables and outdoor ornamentals [EPA Reg. No. 100-RURR, 100-904]

**TO:** Barbara Madden, Team Leader  
Andrew Ertman, Reviewer  
Registration Division (7505P)

Venus Eagle, Product Manager  
Thomas Harris, Reviewer  
Registration Division (7505P)

**THROUGH:** Rosanna Louie-Juzwiak, Risk Assessment Process Leader  
Dana Spatz, Branch Chief  
Environmental Risk Branch 3  
Environmental Fate and Effects Division (7507P)

**FROM:** Tanja Crk, Biologist  
Tiffany Downen, Environmental Engineer  
Environmental Risk Branch 3  
Environmental Fate and Effects Division (7507P)

This memorandum summarizes the ecological exposures and potential risks associated with the proposed uses of emamectin benzoate on outdoor ornamentals (EPA Files Symbol 100-RURR) and Group 9 Cucurbit Vegetables (EPA Reg. No. 100-904). The proposed new application rate for outdoor ornamentals and group 9 cucurbits is 4.80 fl oz of product per acre (0.015 pound of active ingredient per acre [lb a.i./A]) with 6 applications per season, 7 days apart. The maximum seasonal application rate is 0.094 lb a.i./A.

## Summary of Risk Conclusions

### *Proposed Cucurbit and Ornamental Uses*

EFED's assessment of the proposed emamectin benzoate uses indicate that there are LOC exceedances for listed and non-listed marine/estuarine invertebrates on an acute (RQs: 0.44 to 5.28) and chronic basis (RQs: 1.17 to 6.84), and freshwater invertebrates on an acute basis (RQs: 0.05 to 0.21) for listed species for most modeled scenarios. The Oregon nursery standard scenario did not lead to exceedances of the LOC for listed freshwater invertebrates on an acute basis (RQ 0.02) and non-listed marine/estuarine invertebrates on an acute basis (RQ 0.44; an LOC exceedance for listed species).

Acute risk to listed and non-listed birds (RQs: 0.11-0.75) and mammals (RQs: 0.12-0.58) as well as chronic risk to mammals (RQs: 1.31-11.35) is expected as a result of emamectin benzoate use on ornamentals and cucurbits.

No terrestrial plant data have been submitted for emamectin benzoate. As a result, RQs were not calculated for this taxonomic group. In the absence of data, risk to terrestrial plants cannot be precluded.

The acute contact toxicity value for honeybees is an LD<sub>50</sub> of 0.0035 µg a.i./bee (MRID 42851530), which is highly toxic. Based on a foliage residue study, emamectin benzoate can remain lethal to honeybees for 8-24 hours post-application (*i.e.*, 0.015 lb a.i./A spray). Based on these honeybee studies, and the potential emamectin benzoate residues that can occur from the proposed ornamentals and cucurbits uses, EFED is concerned about effects on terrestrial invertebrates.

Emamectin benzoate exists in three different ionic forms, based on dissociation constants at pH 4.2 (benzoic acid) and pH 7.6 (methyldiamino). Given varying reported pH values in aquatic studies, it is uncertain which biologically available chemical form may be more toxic. As emamectin benzoate's solubility and hydrophobicity are influenced by pH, toxicity may also be affected by pH, and no data evaluating the potential relationship between pH and toxicity, or moiety-specific toxicity data, have been submitted. In the absence of moiety- or degradate-specific data, the total toxic residues approach was used and all moieties were assumed to be of equal toxicity. The EPA identified four degradates of concern based on structural similarity to emamectin benzoate that are formed via photolysis:

- (8,9-Z)-4"-epimethylamino-4"-deoxy avermectin B1 (8,9 ZMA isomer);
- 4"-epiamino-4"-deoxyavermectin B1 (AB);
- avermectin B1 monosaccharide (MAB); and
- 4"-epi-(N-formyl)-4"-deoxyavermectin B1 (FAB)

These degradates were assumed to be of equal toxicity to the parent compound.



### *Suggested Label Language Revisions*

Currently proposed label language for honeybees (EPA Reg. No. 100-RURR, cucurbit and ornamental uses):

“This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow drift to blooming crops or weeds if bees are visiting the treatment area.”

Proposed revision:

“This product is highly toxic to bees if exposed to direct treatment or residues on blooming crops or other plants, for up to 24 hours after application. To reduce potential exposure to pollinators that may be visiting the treatment area, do not apply this product or allow drift to blooming, pollen-shedding, or nectar producing parts of plants during this time period.”

Proposed label language addition to ornamental uses label (100-RURR), which is currently part of the cucurbits label (100-904):

“This pesticide is toxic to fish, birds, mammals, and aquatic invertebrates. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash water or rinsate.”

### *Previous Risk Conclusions*

A number of risk assessments have been conducted for emamectin benzoate since the new chemical review completed in 2000 (D226628): new use reviews in 2002<sup>1</sup>, 2005<sup>2</sup>, 2008<sup>3</sup> and 2009<sup>4</sup>, and several Section 18 reviews<sup>5</sup>. Primary risk conclusions identified in previous assessments included potential risks to aquatic and terrestrial invertebrates and mammals.

The principal risks that have been identified previously include risk to estuarine and freshwater invertebrates and small herbivorous and insectivorous mammals at levels of concern (LOC) to the EPA. Potential risk to saltwater fish and insects has also been identified as a concern in these assessments. Chronic risk to mammals was identified in 2002 (DP279840 and 279841) and 2005 (DP309154), and quantified in 2008 (DP 345948).

---

<sup>1</sup> DP barcode 279840 and 279841 (cole crops, leafy vegetables, cotton, and tobacco).

<sup>2</sup> DP barcode 309154, Pome fruits

<sup>3</sup> DP Barcode 345948 Tree nuts and pistachios

<sup>4</sup> DP barcode 351736 Tree Injection

<sup>5</sup> DP barcodes include D223875, D223876, D239671, D239672; D255357, D279840, and D279841

## Data Gaps

Most required studies for emamectin benzoate have been submitted and found to be acceptable or supplemental. For a comprehensive description and justification of data requested, see the most recent problem formulation for Registration Review document (i.e., section entitled 'Anticipated Data Needs' in *Preliminary Problem Formulation for the Environmental Fate, Ecological Risk, Endangered Species, and Drinking Water Exposure Assessments for Emamectin Benzoate*, DP Barcode D385989, June 23, 2011) and Addendum to the Emamectin benzoate Problem Formulation (DP Barcode D397515, January 23, 2012). A summary is provided below:

The following studies were requested in previous new use assessments (DP 309154, S3NU on pome fruits; D381025, S3NU on tree injection Dec. 1, 2010) as well as a part of the registration review of emamectin benzoate.

- Non-GLN Chronic Sediment Toxicity Study  
*Emamectin benzoate is expected to partition to and persist in the sediment and is very highly toxic to aquatic invertebrates and highly toxic to insects. Therefore, there may be potential risk to sediment-dwelling organisms; submission of a chronic sediment study would be valuable to this assessment. Until the final OCSPP guidelines for chronic sediment toxicity tests are published, the registrant should submit a protocol to EFED for approval prior to test initiation.*
- Non-GLN Acute Oral Honeybee Study  
*Submission of an acute oral study in bees would be valuable to this assessment given the high degree of toxicity of emamectin benzoate to bees demonstrated in the contact studies. Although emamectin benzoate has been shown to dissipate from foliage relatively rapidly, it also enters the plant where it forms a reservoir. This reservoir provides extended efficacy, but may also result in increased potential for exposure to the pesticide via the oral route. Emamectin may persist when it is attenuated from sunlight. Therefore, potential for exposure may be extended in some locations. Given that OCSPP guidelines for acute oral studies on bees are not available, the registrant should submit a protocol to EFED for approval prior to test initiation.*
- OCSPP 850.4100 Terrestrial Plant Toxicity Study, Tier I (Seedling Emergence)
- OCSPP 850.4150 Terrestrial Plant Toxicity Study, Tier I (Vegetative Vigor)  
*Terrestrial plant toxicity data have not been submitted. Vegetative vigor and seedling emergence data are needed to assess potential risk to terrestrial plants. In the absence of these data, risk cannot be precluded. However, given the risk estimates for aquatic plants for the proposed uses (on ornamentals and cucurbits) of emamectin benzoate whereby risk to aquatic plants is expected to be low, it is likely that risk to terrestrial plants may be low as well. As a result, the submission of the data may have a low impact to risk conclusions for these proposed uses.*

The following studies were requested as part of the registration review of emamectin benzoate.

- OCSPP 850.2100 Avian Oral Toxicity (Passerine)  
*An avian acute oral toxicity test in passerine species is required. Passerines are the most common birds (in terms of numbers and number of species) in the United States. Many utilize agricultural fields, forests, residential areas and surrounding areas, and, therefore, have the potential to be exposed to pesticides used in agricultural, forest, and residential settings. It is likely that passerines are more likely to be exposed to emamectin benzoate than upland game species and waterfowl. Passerines are smaller and have a higher energy requirement than larger-sized birds. As such, passerines may be more sensitive than other birds, such as the tested mallard duck which has already been found to be sensitive to emamectin benzoate at levels that exceed Agency LOCs for the proposed uses (on ornamentals and cucurbits) of emamectin benzoate. The registrant should submit a protocol to EFED for approval prior to test initiation.*
- OCSPP 850.1075 Fish Acute Toxicity Study  
*There is need for an additional acute warm water fish study with requested analytical sampling (i.e. centrifugation or filtration), preferably with bluegill sunfish. Given that test results for the already submitted bluegill sunfish study (MRID 42743602) are unreliable, that OCSPP Guidance 850.1075 and CFR Part 158 requires a cold water freshwater (e.g., rainbow trout) and a warm water freshwater species, and the potential for variable toxicity across species, it is recommended that an acute warm water fish study be provided, preferably with bluegill sunfish. In the absence of an additional bluegill sunfish study, data available on the rainbow trout (a cold water species) will be used for risk estimation. Given the risk estimates for rainbow trout (acute) and fathead minnow (chronic) for the proposed uses (on ornamentals and cucurbits) of emamectin benzoate whereby risk to freshwater fish is expected to be low, it is likely that risk to bluegill sunfish may be low as well; however, this is an uncertainty. Nevertheless, given this information it is possible that the submission of additional data may have a low impact to risk conclusions for these proposed uses.*

EPA is considering requesting the following studies as part of the registration review of emamectin benzoate, and will be seeking additional input and guidance on these studies, and on the topic of pesticide effects on pollinators in general, from the FIFRA Scientific Advisory Panel (SAP). In the absence of these data and until further guidance is developed on evaluating risk for the honeybee/non-target terrestrial invertebrates, a screening level hazard assessment has been conducted and labeling statement recommendations are included this new use assessment.

- OCSPP 850.3040 Field Testing for Pollinators
- Non-GLN Pollinator Larval Toxicity Study
- Non-GLN Lab Pollinator Chronic Feeding Study
- Non-GLN Residues in Pollen and Nectar / Field Residue Analysis Study



## I. Use Characterization

Emamectin benzoate is an avermectin class insecticide developed for the control of lepidopteran insects. This class of pesticide consists of homologous semi-synthetic macrolides that are derived from the natural fermentation products of *Streptomyces* bacteria. It kills insects by disrupting neurotransmitters, causing irreversible paralysis. It is more effective when ingested, but it also is somewhat effective on contact. When sprayed to foliage, emamectin benzoate penetrates the leaf tissue and forms a reservoir within treated leaves, which provides residual activity against foliage-feeding pests that ingest the substance when feeding.

Emamectin benzoate is currently registered for use on fruiting vegetables, brassica head and stem vegetables, leafy vegetables, pome fruits, tree nuts, and pistachios. Current end use products include an emulsifiable concentrate (Proclaim 0.16 EC), a water soluble concentrate (Proclaim 5 SG), and a tree injection (Proclaim™). It is applied by ground equipment or aerially as a foliar spray, or injected into a tree's vascular system.

The proposed label for emamectin does not give the application rate for the new uses on group 9 cucurbits and outdoor ornamentals in lb a.i./A, but in fluid ounces (fl. oz.) of product per acre. Therefore, this had to be converted to lb a.i./A. Please see **Table 1** below for the rates for the proposed uses from labels 100-904 and 100-RURR.

| Table 1: Proposed uses of Emamectin Benzoate on Outdoor Ornamentals and Group 9 Cucurbits |                                 |                                |                                       |                                   |              |
|-------------------------------------------------------------------------------------------|---------------------------------|--------------------------------|---------------------------------------|-----------------------------------|--------------|
| Use Label (DP Barcode)                                                                    | Maximum Single application rate | Maximum Number of Applications | Minimum Interval between Applications | Seasonal Maximum Application Rate | Percent a.i. |
| Outdoor Ornamentals 100-RURR (396195)                                                     | 0.015 lb a.i. /A                | 6                              | 7 days                                | 0.094 lb a.i./A                   | 5%           |
| Group 9 Cucurbits 100-904 (392511)                                                        | 0.015 lb a.i. /A                | 6                              | 7 days                                | 0.094 lb a.i./A                   | 5%           |

<sup>1</sup> The label gives the maximum application rate in oz of product/A.

## II. Environmental Fate and Ecological Effects Characterization

The environmental fate and toxicity of emamectin benzoate have been discussed in depth in EPA's ecological problem formulation in support of registration review; refer to the *Preliminary Problem Formulation for the Environmental Fate, Ecological Risk, Endangered Species, and Drinking Water Exposure Assessments for Emamectin Benzoate*, DP Barcode D385989, June 23, 2011.

### a. Environmental Fate Characterization

Emamectin benzoate consists of a mixture of at least 90% 4"-epi-methylamino-4"-deoxyavermectin B<sub>1a</sub> and a maximum of 10% 4"-epi-methylamino-4"-deoxyavermectin B<sub>1b</sub> benzoate. The available chemical properties and environmental fate data are primarily on the B<sub>1a</sub> component; because both the B<sub>1a</sub> and B<sub>1b</sub> components have very similar structures, their physicochemical properties, fate, and toxicity profiles are assumed to be similar.

Based on available data, emamectin benzoate is less persistent in aerobic soil environments (half-lives range from 50.2 days to 193.4 days) than in anaerobic soil environments (427 days). Emamectin benzoate is stable to hydrolysis, but is susceptible to photolysis. The primary environmental dissipation pathway is expected to be through photolysis on soil (half-life 5 days).

Mobility studies conducted with emamectin benzoate indicate that the parent compound and its degradates are expected to be relatively immobile in the environment due to a high degree of sorption to soil particles ( $K_d$  219 to 2037). Therefore, most of the emamectin benzoate that enters the terrestrial environment is expected to remain at the site of application until it degrades or is transported via soil erosion. For this reason, high levels of parent and/or transformation products are not expected to enter surface water through runoff or to leach into ground water. Emamectin benzoate's low vapor pressure and Henry's law constant suggest that volatility from soil and water, respectively, will be low.

Some of emamectin benzoate's properties are pH dependent. For example, its water solubility is 320 mg/L at pH 5, 93 mg/L at pH 7, and 0.1 mg/L at pH 9. Similarly, its log  $K_{ow}$  is 5.0 at pH 7 and 5.9 at pH 9.

## **b. Ecological Effects Data**

The following is a summary of the available terrestrial and aquatic organism data used to evaluate the proposed uses. A detailed summary of the available terrestrial and aquatic ecotoxicity data for emamectin benzoate is provided in **Appendix 1**.

### Terrestrial Organisms

#### *Birds*

Representative avian acute oral (14-day LD<sub>50</sub>: 46 mg a.i./kg-bw; MRID 42743601) and sub-acute dietary (8-day LC<sub>50</sub>: 570 mg a.i./kg-diet; MRID 42851528) study results indicate the sensitivity of the mallard duck to technical grade emamectin benzoate is high and moderate on an acute basis, respectively. Representative avian 2-generation reproduction (NOAEC: 40 mg a.i./kg-diet; MRID 44007910) study results indicate no effect in the mallard duck. Three additional studies (MRID 42868905, 42851527, and 44007911) with the Northern bobwhite quail indicate reduced sensitivity to emamectin benzoate relative to the mallard.

#### *Mammals*

Emamectin benzoate is highly toxic to mammals on an acute basis; the mouse study (MRID 42743612) indicated that the male (♂LD<sub>50</sub>: 22 mg a.i./kg-bw) was more sensitive than the female (♀LD<sub>50</sub>: 31 mg a.i./kg-bw) and that additional toxic signs were tremors, ataxia (*i.e.*, loss of muscle coordination), bradypnea (*i.e.*, abnormally slow breathing rate), and loss of the righting reflex. Emamectin benzoate is also toxic on a chronic basis; treatment-related toxicity was observed in the 2-generation reproduction rat study (NOAEL: 0.6 mg/kg-bw; MRID 42851511). For additional information on the specific effects to mammals observed in these studies, and the potential for heightened sensitivities (e.g., neurological effect) from emamectin benzoate to mammalian populations lacking adequate P-glycoprotein expression, refer to **Appendix 1**.

#### *Terrestrial invertebrates*

Emamectin benzoate is highly toxic to bees on an acute contact basis (96-hr LD<sub>50</sub>: 0.0035 µg a.i./bee; MRID 42851530) and foliar residues can remain lethal for 8-24 hours post-application (MRID 43393006, based on a spray application rate of 0.015 lb a.i./A).

#### *Terrestrial plants*

No terrestrial plant data have been submitted for emamectin benzoate; therefore, there is uncertainty as to the potential effects emamectin benzoate may have on non-target terrestrial plants.



## Aquatic Organisms

### *Acute: Fish, invertebrates, and aquatic phase amphibians*

Emamectin benzoate is categorized as highly toxic to freshwater fish (rainbow trout, 96-hr  $LC_{50}$ : 174  $\mu\text{g a.i./L}$ ; MRID 42851529), moderately toxic to saltwater fish (sheepshead minnow, 96-hr  $LC_{50}$  1430  $\mu\text{g a.i./L}$ ; MRID 43393003), very highly toxic (waterflea, 48-hr  $EC_{50}$ : 1.0  $\mu\text{g a.i./L}$  MRID 42743603; mysid, 96-hr  $LC_{50}$ : 0.04  $\mu\text{g a.i./L}$  MRID 43393001) and highly toxic (eastern oyster, 96-hr  $EC_{50}$ : 490  $\mu\text{g a.i./L}$  MRID 43393002) to aquatic invertebrates. To date, there are no available toxicity data to assess potential risk to sediment dwelling organisms. Based on the expected affinity of emamectin benzoate to sediment and the sensitivity of aquatic organisms to the compound, there is the potential for effects on sediment-dwelling organisms.

In addition to the trout acute toxicity study, there are also two additional freshwater fish studies (fathead minnow, MRID 43850106; and, bluegill sunfish, MRID 42743602) of comparable (*i.e.*, highly toxic), but slightly lower toxicities than for trout, 96-hour  $LC_{50}$  194  $\mu\text{g total/L}$  and 180  $\mu\text{g a.i./L}$ , respectively. Furthermore, they are supplemental studies: in the fathead minnow study suspended particulates were not removed (via filtration or centrifugation) prior to extraction and chemical analysis; in the bluegill study the test material concentrations fluctuated excessively during the study, which would not permit accurate measures of toxicity. Given that test results for the submitted bluegill sunfish study (MRID 42743602) are unreliable, that OCSPP Guidance 850.1075 and CFR Part 158 requires a cold water freshwater (trout) and a warm water freshwater species, and the potential for variable toxicity across species, it is recommended that an acute warm water fish study be provided, preferably with bluegill sunfish. The rainbow trout study provides a preliminary estimate of effect to freshwater fish species, but the bluegill sunfish may be found to be either more or less sensitive to emamectin benzoate, which can only be confirmed by additional testing.

An important uncertainty is that of the effect of pH on toxicity (brought up in memo dated August 29, 1997, DP Barcode: D228080). Emamectin benzoate exists in three different ionic forms, based on dissociation constants at pH 4.2 (benzoic acid) and pH 7.6 (methyamino). The ionic form of benzoic acid predominating below pH 4.2 is not within normal biological range of aquatic habitats; hence, only two chemical forms are of toxicological concern. Between pH 4.2 and 7.6, greater than 50% of the methylamine moiety is a protonized amine. About 90% protonization of this chemical occurs at pH 6.7 and decreases to 50% at pH 7.6. The third form of emamectin benzoate occurs at pH levels greater than pH 7.6 predominantly as a non-protonized methylamine. Given varying reported pH values in aquatic studies, it is uncertain which biologically available chemical form may be more toxic. At pH 7, emamectin benzoate has an octanol/water partition coefficient (log P) value of 5.0. Chemicals with a log P of 5 are a concern for adsorption to particulates. Both water solubility and the octanol water partition coefficient (log  $P_{ow}$ ) change with pH (*i.e.*, water solubility decreases sharply and log P increases dramatically). Solubility and hydrophobicity are greatly influenced by pH. Therefore, toxicity may also be affected by pH, and no data evaluating the potential relationship between pH and toxicity, or moiety-specific toxicity data, have been submitted. All moieties are assumed to be of equal toxicity in this assessment. As a result, it is possible if one moiety is more toxic or less

toxic than another, the risk could be under- or over-estimated, respectively, for aquatic organisms.

*Chronic: Fish, invertebrates, and aquatic phase amphibians*

A freshwater fish early life-stage test using the TGAI (fathead minnow, NOAEC: 6.5 µg a.i./L MRID 43850107) suggests that emamectin benzoate affects larvae survival and fish growth at concentrations between 6.5 and 12 µg a.i./L. A chronic toxicity study in saltwater fish has not been submitted; therefore, the chronic toxicity of emamectin benzoate to saltwater fish was estimated using an acute-to-chronic ratio (ACR) derived for fathead minnows (96-hr LC<sub>50</sub> of 194 µg total/L [MRID 43850106] ÷ NOAEC of 6.5 µg a.i./L [MRID 43850107] = 30 µg a.i./L; dividing the 96-hour LC<sub>50</sub> of 1430 µg a.i./L [sheepshead minnow, MRID 43393003] by the ACR leads to a chronic endpoint, NOAEC, estimate for the sheepshead minnow of 48 µg a.i./L).

It is uncertain to what extent the fathead minnow acute endpoint is applicable for this ACR calculation. The LC<sub>50</sub> was extrapolated from a single partial mortality of 5% and test concentrations in the study (MRID 43850106) are uncertain, because water samples were not filtered or centrifuged and extracted prior to chemical analysis to remove particulates to which emamectin benzoate may adhere. Results reported in the fish early life study (MRID 43850107) demonstrate that emamectin benzoate readily sorbs to particulates, organic matter and glass surfaces necessitating the use of centrifugation prior to analytical determination. Application of this ACR derived for fathead minnows assumes that the ACR is conserved across fish species. If the ACR in saltwater fish is higher or lower than the ACR derived for fathead minnows, then toxicity could be under- or over-estimated, respectively. Since the bioavailable (or, completely dissolved) concentration is not known for the acute study, the concentration is presented as a 'total' residue, which may underestimate the potential toxicity value for the organism that is exposed.

A waterflea life-cycle study using the TGAI (NOAEC: 0.088 µg a.i./L; MRID 43393004) suggests that emamectin benzoate affects egg production, young survival, and growth at concentrations between 0.088 and 0.16 µg a.i./L. Two supplemental estuarine/marine invertebrate life-cycle toxicity tests using the TGAI were submitted (MRID 44305601, 45833001). MRID 45833001 produced the lowest NOAEC of 0.0087 µg a.i./L; the LOAEC was 0.013 µg a.i./L based on reduced growth. However, emamectin concentrations were considerably lower after Day 14 of the study. Had the exposure concentrations been maintained at a constant level during the entire 28-day study duration, effects may have occurred at or below the identified NOAEC. Therefore, the 28-day mean concentration can be used to calculate risk quotients; however, the mean emamectin benzoate concentration achieved during the latter part of the study (0.0049 µg a.i./L at the mean measured NOAEC of 0.0087 µg a.i./L) could represent a lower bound NOAEC and can be used for risk characterization for the mysid.

*Aquatic plants*

Two aquatic plant studies were submitted. One study was submitted for non-vascular (freshwater algae, 5-day EC<sub>50</sub>>3.9 µg a.i./L; MRID 43850108) plant species and one study was

submitted for vascular (duckweed, 14-day  $EC_{50} > 94 \mu\text{g a.i./L}$ ; MRID 43850109) plant species. The  $EC_{50}$  values are greater than the highest concentration tested. There was a 13% reduction in algal growth at the highest concentration tested in the freshwater algae study. In both studies, the endpoints are based on initial measured test concentrations. According to a memo dated August 29, 1997 (DP Barcode: D228080), uncertainties exist about the measured test concentrations of these two aquatic studies, to the point where filtration and centrifugation methods are encouraged in future aquatic studies with emamectin benzoate. Additional concerns about toxicity and pH effects on solubility, partitioning, and ionic form of emamectin benzoate in aquatic environments are also discussed.

### III. Exposure Estimates and Analysis

The application rate, applications per season, and reapplication intervals are used to estimate exposure concentrations (EECs), which are then compared to the toxicity data (Appendices 2 and 4, respectively).

In the absence of moiety- or degradate-specific data, the total toxic residues approach was used; the environmental fate data parameters for modeling were determined using the *Guidance for Selecting Input Parameters in Modeling the Environmental Fate and Transport of Pesticides*, Version 2.1, October 22, 2009 and the draft *Guidance for Modeling Pesticides Total Toxic Residues (TTR)* May 20, 2009.

Half-lives for the total residues of toxicological concern are calculated by adding the residues of the parent compound, with residues from the degradates of concern (in terms of percent of the applied radiation) for each sampling interval. These totals are converted into natural logs, and plotted against time. The slope of the regression line from that plot is used to calculate the new half-life ( $\ln(2)/k$ ; when  $k$  is the slope of the regression line).

The EPA identified four degradates of concern based on structural similarity to emamectin benzoate that are formed via photolysis (MARC memo references: D238206, September 2, 1997; D255357, August 20, 2001; D277085, August 20, 2001):

- (8,9-Z)-4"-epimethylamino-4"-deoxy avermectin B1 (8,9 ZMA isomer);
- 4"-epiamino-4"-deoxyavermectin B1 (AB);
- avermectin B1 monosaccharide (MAB); and
- 4"-epi-(N-formyl)-4"-deoxyavermectin B1 (FAB)

#### *Aquatic Exposures*

The EECs in surface water concentrations were estimated with the Tier II PRZM (Version 3.12.2) and EXAMS (version 2.98.04.06) models linked by the program PE5 (Version 01 compiled 07/23/07). PRZM simulates pesticide fate and transport as a result of leaching, direct spray drift, runoff and erosion from an agricultural field. The EXAMS model simulates pesticide loading via runoff, erosion, and spray drift into a "standard" farm pond. Detailed description, documentation, and direct links for running these models can be found in:



<http://www.epa.gov/oppefed1/models/water/index.htm>. The chemical properties for emamectin benzoate, and input values used for PRZM/EXAMS, are summarized in Appendix 2. The full PRZM/EXAMS output file is in Appendix 4.

Previously, only one soil metabolism value was available to determine the soil metabolism half-life. Submitted with this new use were three new aerobic soil metabolism studies (MRID 48480101, 48480102, 48480103). These studies were deemed supplemental because foreign soils were used without indication that they are representative of US soils. One soil was deemed invalid for use because the study was not run long enough to determine a proper half-life. In prior assessments, the calculated aerobic soil half-life input value was 579 days, and 1,158 days for aerobic aquatic half-life. When considering the additional aerobic soil metabolism half life values, the new values are 107.5 days for the aerobic soil half-life input, and 215 days for the aerobic aquatic half-life). The method for determining the half-lives was consistent with the Input Parameter Guidance

([http://www.epa.gov/oppefed1/models/water/input\\_parameter\\_guidance.htm](http://www.epa.gov/oppefed1/models/water/input_parameter_guidance.htm)). For more information on the model inputs see Appendix 2.

The maximum peak, 21-day, and 60-day means for the outdoor ornamental and group 9 cucurbit uses are summarized in Table 2. For the outdoor ornamentals, the California nursery scenario produced the highest peak concentration (0.211 µg/L), and the highest 21-day (0.059 µg/L) and 60-day (0.052 µg/L) means. For the Group 9 cucurbits, the Florida cucumber scenario resulted in the peak concentration (0.053 µg/L), and the 21-day (0.026 µg/L) and 60-day (0.018 µg/L) means. The PRZM/EXAMS scenarios and respective EECs are summarized in Table 2.

| Crop or Crop Group  | Maximum Application Rate<br>lbs./acre | Total (season or crop)<br>lbs./acre | Minimum Application Interval<br>(days) | Scenario (State crop)<br>Scenario | 1 <sup>st</sup> Application date<br>(m-d-y) | Application Method | EECs (µg/L)  |              |              |
|---------------------|---------------------------------------|-------------------------------------|----------------------------------------|-----------------------------------|---------------------------------------------|--------------------|--------------|--------------|--------------|
|                     |                                       |                                     |                                        |                                   |                                             |                    | Peak         | 21 day       | 60 day       |
| Outdoor Ornamentals | 0.015                                 | 6                                   | 7                                      | CAnurserySTD                      | 1-Apr                                       | Aerial             | <b>0.211</b> | <b>0.059</b> | <b>0.052</b> |
|                     |                                       |                                     |                                        | FLnurserySTD                      | 2-Jan                                       |                    | 0.071        | 0.023        | 0.021        |
|                     |                                       |                                     |                                        | MinurserySTD                      | 2-Jan                                       |                    | 0.059        | 0.033        | 0.032        |
|                     |                                       |                                     |                                        | NJnurserySTD                      | 2-Jan                                       |                    | 0.085        | 0.037        | 0.036        |
|                     |                                       |                                     |                                        | ORnurserySTD                      | 2-Jan                                       |                    | 0.017        | 0.010        | 0.010        |
|                     |                                       |                                     |                                        | TNnurserySTD                      | 15-Apr                                      |                    | 0.117        | 0.046        | 0.045        |
| Group 9 Cucurbits   | 0.015                                 | 6                                   | 7                                      | FLcucumberSTD                     | 5-Dec***                                    | Aerial             | <b>0.053</b> | <b>0.026</b> | <b>0.018</b> |

\*Values in bold are the most conservative values.

\*\*Application method for this label includes ground, airblast, and aerial. To be conservative, the aerial application method was evaluated.

\*\*\* The date of the first application for the Florida cucurbit scenario for foliar application suggests a start date of December 5<sup>th</sup>. However, since there are 6 applications with 7 day intervals, that pushes the 6<sup>th</sup> application into the next calendar year. Currently, PRZM/EXAMS cannot handle calculating applications going from one calendar year to the next. To attempt to determine the EECs for that time period (since weather data is based on the time of application as well as location etc.), the first application was made in January, and the remaining applications took place in December.

### Terrestrial Exposures

Terrestrial wildlife exposure estimates are typically estimated for birds and mammals following the methods of Hoerger and Kenaga (1972) as modified by Fletcher *et al.* (1994). The

conceptual framework for this method of estimating terrestrial exposure assumes that organisms are exposed to a single pesticide residue via dietary routes in a specific exposure scenario.

**Table 3** summarizes the terrestrial EECs for the proposed new uses. An application rate of 0.015 lb a.i./A was considered in T-REX (v1.4.1); 6 applications with a 7 day interval. The EECs were converted to an oral dose and compared with the oral toxicity data. The risk assessment for emamectin benzoate uses upper bound (*i.e.*, 90<sup>th</sup> percentile) predicted residues as the measure of exposure. The predicted upper bound residues that may be expected to occur immediately following application to ornamentals and cucurbits are presented in **Table 3**.

| Table 3. EECs on Potential Food Items Following Label-Specified Applications of Emamectin benzoate Using the T-REX Model (ppm). |                                 |               |
|---------------------------------------------------------------------------------------------------------------------------------|---------------------------------|---------------|
| USE                                                                                                                             | DIETARY-BASED <sup>1</sup> EECs | KENAGA VALUES |
|                                                                                                                                 |                                 | Upper Bound   |
| <i>Maximum Application rate 0.015 lb a.i./A, 6 apps with a 7 day interval</i>                                                   |                                 |               |
| Ornamentals & Cucurbits                                                                                                         | Short Grass                     | 15.71         |
|                                                                                                                                 | Tall Grass                      | 7.20          |
|                                                                                                                                 | Broadleaf Plants/Small Insects  | 8.83          |
|                                                                                                                                 | Fruits/Pods/Seeds/Large Insects | 0.98          |
| <sup>1</sup> Dose-based EECs are provided in Appendix 5.                                                                        |                                 |               |

TerrPlant (Version 1.1.2) is used to calculate EECs for non-target plant species inhabiting dry and semi-aquatic areas. No terrestrial plant data have been submitted for emamectin benzoate; therefore, TerrPlant was not run for this assessment.

#### IV. Risk Estimation /Description

Risk characterization integrates EECs and toxicity estimates to determine whether the proposed uses pose risk to non-target species above levels of concern (LOC). In a deterministic approach, an exposure estimate is divided by a single point estimate of toxicity to calculate a risk quotient (RQ). The RQ is then compared to LOCs, which serve as criteria for categorizing potential risk to non-target organisms (see **Appendix 3**).

##### *Non-target Aquatic Animals and Plants*

Acute and chronic RQs calculated for fish (freshwater and estuarine/marine), aquatic invertebrates (freshwater and estuarine/marine), and RQs for aquatic plants (vascular and non-vascular) are given in Appendices 1 and 5. Acute risk quotients were  $\leq 0.01$  for freshwater fish, and marine/estuarine fish. Acute fish RQs were less than the LOC for endangered species (0.05). Chronic RQs for freshwater fish and marine/estuarine fish were between  $\leq 0.01$ , below the LOC of 1.0. Acute RQs for aquatic invertebrates ranged from 0.05 to 0.21 for freshwater species and 1.33 to 5.28 for marine/estuarine species. For both uses, RQs for marine/estuarine species exceeded the LOC for endangered species and non-listed species and only for endangered species for freshwater invertebrates. Chronic RQs for aquatic invertebrates ranged from 0.21 to 0.68 for freshwater species and 2.09 to 6.84 for marine/estuarine species. The RQs for freshwater invertebrates were below the chronic LOC of 1.0, but marine/estuarine invertebrates were all

above the LOC. RQs for non-vascular aquatic plants were <0.01; RQs for vascular aquatic plants were <0.01. The aquatic RQs that exceeded the LOCs for aquatic organisms were for the following: listed/non-listed marine/estuarine invertebrates for all of the modeled scenarios on an acute basis, listed marine/estuarine invertebrates for all of the modeled scenarios on a chronic basis, and listed freshwater invertebrates for all scenarios on an acute basis.

#### *Non-target Terrestrial Animals and Plants*

For birds, dose-based acute RQs that exceeded Agency LOCs ranged from 0.11 to 0.75; however, dietary-based RQs ranged from <0.01 to 0.03, and chronic dietary-based RQs ranged from 0.02 to 0.39. For mammals, acute dose-based RQs that exceeded EPA's LOCs ranged from 0.12 to 0.58. Chronic dietary-based RQ that exceeded the LOC was 1.31 for short grass, and the chronic dose-based RQs that exceeded the LOCs ranged from 2.38 to 11.35. All studies used for the RQ calculations indicated adverse effects to the test organisms except for the avian reproduction study on the mallard duck (see **Appendix 1**; MRID 44007910); LOC exceedances were not observed for birds on a chronic basis. Given the RQ calculations and exceedances (see **Appendix 5**), acute risk to non-target listed and non-listed birds and mammals, as well as chronic risk to mammals, are expected as a result of emamectin benzoate use on ornamentals and cucurbits.

No terrestrial plant data have been submitted for emamectin benzoate. As a result, RQs were not calculated for this taxonomic group. In the absence of data, risk to terrestrial plants cannot be precluded. However, submission of seedling emergence and vegetative vigor studies would reduce uncertainty in characterizing risk for terrestrial plants.

The acute contact toxicity value for honeybees is an LD<sub>50</sub> of 0.0035 µg a.i./bee (MRID 42851530), which is highly toxic. Risk estimations for terrestrial invertebrates are not routinely conducted. A residue on foliage study indicates that emamectin benzoate will remain lethal to honeybees for 8-24 hours post-application (*i.e.*, 0.015 lbs a.i./A spray). Based on these honeybee studies, there is concern about potential adverse effects to terrestrial invertebrates as a result of emamectin benzoate use on ornamentals and cucurbits.

#### **Incident Reports**

Three incidence databases are available: 1) maintained and catalogued by EFED in the Ecological Incident Information System v. 2.1.1 (EIIS), which was last updated Oct. 15, 2010 but contains incident reports since 1994; 2) the American Bird Conservancy and USEPA program maintaining the Avian Incident Monitoring System (AIMS), which was last updated June 2005; and, 3) the Incident Data System (IDS), a component of the PRISM database, which was checked for incidences occurring in the last three years.

No incidents have been reported (*i.e.*, no records were found) in which emamectin benzoate has been associated with some type of environmental effect. This is the case for all three incident databases searched. The absence of documented incidents does not necessarily mean that such incidents did not occur. Mortality incidents must be seen, reported, investigated, and submitted



to the Agency in order to be recorded in the incident databases. In addition, incident reports for non-target organisms typically provide information only on mortality events and plant damage. Sublethal effects in organisms such as abnormal behavior, reduced growth and/or impaired reproduction are rarely reported, except for phytotoxic effects in terrestrial plants.

### LOCATES Output

LOCATES (v.2.2) was run using the following crop listings: [for *cucurbits*] cucumbers and pickles, okra, bittermelons, muskmelons and pepinos, cantaloupe, pumpkins, squash-summer, squash-winter, watermelons; [for *ornamentals*] Christmas trees, Christmas trees cut, floriculture crops. Tables 4a and 4b provide a summary of the LOCATES output. However, in addition to this information, the LOCATES output includes a comprehensive listing of species scientific names and species counts specific for each state; this additional information is available upon request.

**Table 4a. Number of Endangered Species Potentially Exposed to Emamectin Benzoate with the Proposed Uses**

|                 | Mammal | Bird | Amphibian | Reptile | Fish | Crustacean | Bivalve | Gastropod | Arachnid | Insect | Dicot |
|-----------------|--------|------|-----------|---------|------|------------|---------|-----------|----------|--------|-------|
| <b>Counties</b> | 947    | 334  | 152       | 254     | 787  | 74         | 544     | 50        | 5        | 32     | 917   |
| <b>Species</b>  | 35     | 8    | 21        | 20      | 111  | 21         | 71      | 24        | 11       | 13     | 655   |
| <b>States</b>   | 43     | 16   | 12        | 30      | 40   | 13         | 30      | 12        | 2        | 10     | 48    |

**Table 4b. Number of Endangered Species Potentially Exposed to Emamectin Benzoate with the Proposed Uses**

|                 | Monocot | Ferns | Conf/Cycds | Coral | Lichen |
|-----------------|---------|-------|------------|-------|--------|
| <b>Counties</b> | 520     | 54    | 8          | 30    | 22     |
| <b>Species</b>  | 67      | 27    | 3          | 2     | 2      |
| <b>States</b>   | 45      | 10    | 3          | 3     | 5      |

## APPENDIX 1.

### Toxicological Endpoints and Summary of Risks

| Assessment Endpoint                                                                                    | Measures of Effect                                   | Species                                                                               | Toxicity Value                                                                                            | Endpoint                                                                                                                                                                                                                                                                   | Reference / Study classification                                        |
|--------------------------------------------------------------------------------------------------------|------------------------------------------------------|---------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|
| <b>Birds:</b><br>Abundance (i.e., survival, reproduction, and growth) of individuals and populations   | Avian acute oral LD <sub>50</sub> 14-days            | Mallard duck ( <i>Anas platyrhynchos</i> )                                            | LD <sub>50</sub> : 46 mg a.i./kg-bw<br>NOAEC: <12 mg a.i./kg-bw <sup>1</sup>                              | Lethality<br><br>Reduced bw gain and clinical signs of neurotoxicity were observed at all tested concentrations.                                                                                                                                                           | MRID 42743601<br>Acceptable<br><br><i>Highly toxic</i> <sup>†</sup>     |
|                                                                                                        | Avian sub-acute dietary LC <sub>50</sub> 8-days      | Mallard duck ( <i>Anas platyrhynchos</i> )                                            | LC <sub>50</sub> : 570 mg a.i./kg-diet<br>NOAEC: 20 mg a.i./kg-diet                                       | Lethality<br><br>Clinical signs of neurotoxicity were observed at >20 mg a.i./kg-diet                                                                                                                                                                                      | MTID 42851528<br>Acceptable<br><br><i>Moderately toxic</i> <sup>A</sup> |
|                                                                                                        | Avian reproduction NOAEL 2-generation                | Mallard duck ( <i>Anas platyrhynchos</i> )                                            | NOAEC: 40 mg a.i./kg-diet<br>LOAEC > 40 mg a.i./kg-diet                                                   | No adverse effects observed at doses tested                                                                                                                                                                                                                                | MRID 44007910<br>Supplemental <sup>2</sup>                              |
| <b>Mammals:</b><br>Abundance (i.e., survival, reproduction, and growth) of individuals and populations | Mammalian acute oral LD <sub>50</sub> ♦              | Laboratory mouse ( <i>Mus musculus</i> )<br>(study wt ave@ day 0 for ♂ mice = 28.9 g) | ♂ LD <sub>50</sub> : 22 mg a.i./kg-bw<br>♀ LD <sub>50</sub> : 31 mg a.i./kg-bw                            | Lethality                                                                                                                                                                                                                                                                  | MRID 42743612<br>Acceptable<br><br><i>Highly toxic</i> <sup>†</sup>     |
|                                                                                                        | Mammalian acute inhalation toxicity LC <sub>50</sub> | Rat                                                                                   | LC <sub>50</sub> > 5.0 mg/L<br>(for MK-0243 0.16 lbs/gal EC formulation and the vehicle control EC)       | Thin appearance, rough coat, hunched posture, nasal and ocular discharge, dyspnea, tremors, lethargy, and dehydration. Of the 5 mortalities, histopathology revealed necrotizing rhinitis of the nose and congestion, edema, and diffuse alveolar hemorrhage of the lungs. | MRID 42743608<br>Acceptable<br><br><i>Toxicity Category IV</i>          |
|                                                                                                        |                                                      | Rat                                                                                   | ♂ LC <sub>50</sub> > 1.049 mg/L<br>0.239 < ♀ LC <sub>50</sub> < 0.506 mg/L<br>(for technical, 96.2% a.i.) | Mortality<br><br>Salivation, reduced stability, hunched posture, shaking, piloerection, upper respiratory tract irritation.                                                                                                                                                | MRID 47002107<br>Acceptable<br><br><i>Toxicity Category II</i>          |
|                                                                                                        |                                                      | No Data                                                                               | No Data                                                                                                   | No Data                                                                                                                                                                                                                                                                    | MRID 47153907<br>Waived                                                 |
|                                                                                                        |                                                      | Rat                                                                                   | ♂ LC <sub>50</sub> > 2.54 mg/L<br>♀ LC <sub>50</sub> > 2.54 mg/L<br>(for formulation, 4.0% a.i.)          | No Mortality.<br>Weight gain, one ♂ had red ocular discharge, one ♀ had irregular respiration/hypoactive.                                                                                                                                                                  | MRID 47309305<br>Acceptable<br><br><i>Toxicity Category IV</i>          |



| Assessment Endpoint                            | Measures of Effect                               | Species                                         | Toxicity Value                                                                                                                                                   | Endpoint                                                                                                                                  | Reference / Study classification                                    |
|------------------------------------------------|--------------------------------------------------|-------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|
|                                                | Mammalian reproductive NOAEL 2- generation ♦     | Sprague-Dawley Rat ( <i>Rattus norvegicus</i> ) | NOAEL: 0.6 mg/kg-bw/day<br>LOAEL=1.8 mg/kg/day                                                                                                                   | Based on decreased fecundity and fertility indices and clinical signs (tremors and hind limb extension) in offspring of both generations. | MRID 42851511<br>Acceptable                                         |
| <u>Insect:</u><br>Survival of populations      | Honey bee acute contact LD <sub>50</sub> 96-hour | Honey bee ( <i>Apis mellifera</i> )             | LD <sub>50</sub> 3.5 ng a.i./bee<br>(0.0035 µg a.i. /bee)<br>NOAEC = 0.8 ng a.i./bee<br>(0.0008 µg a.i. /bee)                                                    | Lethality                                                                                                                                 | MRID 42851530<br>Acceptable<br><br><i>Highly toxic</i> <sup>‡</sup> |
|                                                | Residues on foliage 24-hour                      | Honey bee ( <i>Apis mellifera</i> )             | Sprayed at 0.015 lbs ai/A remain lethal to honeybees for 8 to 24 hours post-application<br><br>At 3-hr, 99.6% died<br>At 8-hr, 46.1% died<br>At 24-hr, 2.5% died | Lethality                                                                                                                                 | MRID 43393006<br>Acceptable                                         |
| <u>Terrestrial plants:</u> Survival and growth | Seedling emergence EC <sub>25</sub>              | No data                                         | No data                                                                                                                                                          | No data                                                                                                                                   | No data                                                             |
|                                                | Seedling emergence NOAEC                         |                                                 |                                                                                                                                                                  |                                                                                                                                           |                                                                     |
|                                                | Vegetative vigor EC <sub>25</sub>                |                                                 |                                                                                                                                                                  |                                                                                                                                           |                                                                     |
|                                                | Vegetative vigor NOAEC                           |                                                 |                                                                                                                                                                  |                                                                                                                                           |                                                                     |

<sup>1</sup> Reduced body weight and clinical signs of neurotoxicity was observed at all dosages. The NOAEC for mortality was 12 mg a.i./kg-bw

<sup>2</sup> Considered supplemental since LOAEC values were not determined.

<sup>†</sup> Acute Oral (avian/mammal): Based on LD<sub>50</sub> (mg/kg) <10 very highly toxic; 10-50 highly toxic; 51-500 moderately toxic; 501-2000 slightly toxic; >2000 practically nontoxic

<sup>Δ</sup> Acute Dietary (avian): Based on LC<sub>50</sub> (mg/kg) <50 very highly toxic; 50-500 highly toxic; 501-1000 moderately toxic; 1001-5000 slightly toxic; >5000 practically nontoxic

<sup>§</sup> Based on acute contact LD<sub>50</sub> (µg a.i./bee) <2 highly toxic; 2-10.99 moderately toxic; ≥11 practically non-toxic

♦The mouse study (MRID 42743612) indicated that the male was more sensitive than the female and that additional toxic signs were tremors, ataxia (*i.e.*, loss of muscle coordination), bradypnea (*i.e.*, abnormally slow breathing rate), and loss of the righting reflex. Treatment-related toxicity was observed in the 2-generation reproduction rat study (MRID 42851511), whereby the rat exposed to emamectin benzoate (B1, benzoate salt) included decreased body weight gain and neuronal degeneration in the brain and spinal cord in both sexes and generations, decreased fecundity and fertility indices, and tremors and hind limb extension in the offspring of both generations. Several populations of mammals lacking adequate P-glycoprotein (P-gp) expression including CF-1 mice, a small population of humans, and collie dogs are considered highly sensitive to the neurological effects of emamectin (Lankas *et al.* 1997, Habashi 2006, Kerb 2005). P-gp resides in the plasma membrane and actively transports (Marzolini *et al.* 2004) foreign substances from within the cell out for excretion outside the body; without its activity a buildup of foreign chemicals could occur in the brain, gonads, and fetus. It is uncertain which additional populations of mammals are particularly sensitive to emamectin due to inadequate expression of P-gp.



| Assessment Endpoint                                                                                    | Measures of Effect                                               | Species                                                                                | Toxicity Value*                                             | Study classification (Selection basis)                                                                                                                                           | Reference                                                                       |
|--------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|----------------------------------------------------------------------------------------|-------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|
| <u>Freshwater fish:</u><br>Survival and reproduction of individuals and communities                    | Freshwater fish acute LC <sub>50</sub><br>96-hr                  | Rainbow trout ( <i>Oncorhynchus mykiss</i> )                                           | LC <sub>50</sub> : 174 µg a.i./L<br>NOAEC: 30 µg a.i./L     | Lethality<br><br>NOAEC based on 20% mortality at 49 µg a.i./L                                                                                                                    | MRID 42851529<br><b>Acceptable</b><br><br><i>Highly toxic</i> <sup>†</sup>      |
|                                                                                                        | Freshwater fish early life-stage NOAEC                           | Fathead Minnow ( <i>Pimephales promelas</i> )                                          | NOAEC: 6.5 µg a.i./L<br>LOAEC: 12 µg a.i./L                 | Reproduction; growth<br><br>74% reduction in larvae survival<br>9% reduction in total length<br>27% reduction in wet wt.<br>26% reduction in dry wt.<br>21% reduction in biomass | MRID 43850107<br><b>Acceptable</b>                                              |
| <u>Freshwater invertebrates:</u><br>Survival and reproduction of individuals and communities           | Freshwater invertebrate acute EC <sub>50</sub><br>48-h           | Waterflea <sup>2</sup> ( <i>Daphnia magna</i> )<br><br>Flow-through                    | EC <sub>50</sub> : 1.0 µg a.i./L<br>NOAEC: 0.3 µg a.i./L    | Immobilization<br><br>10% immobilization occurred at 0.47 µg a.i./L                                                                                                              | MRID 42743603<br><b>Acceptable</b><br><br><i>Very highly toxic</i> <sup>†</sup> |
|                                                                                                        | Freshwater invertebrate life cycle NOAEC                         | Waterflea ( <i>Daphnia magna</i> )<br><br>Flow-through                                 | NOAEC: 0.088 µg a.i./L<br>LOAEC: 0.16 µg a.i./L             | Reproduction; growth<br><br>Egg production, young survival, and growth were affected.                                                                                            | MRID 43393004<br><b>Acceptable</b>                                              |
| <u>Estuarine and marine fish:</u><br>Survival and reproduction of individuals and communities          | Estuarine and marine acute LC <sub>50</sub><br>96-h              | Sheepshead minnow ( <i>Cyprinodon variegatus</i> )                                     | LC <sub>50</sub> : 1430 µg a.i./L<br>NOAEC: 860 µg a.i./L   | Lethality<br><br>NOAEC based on 60% mortality at the 1430 µg a.i./L                                                                                                              | MRID 43393003<br><b>Acceptable</b><br><br><i>Moderately toxic</i> <sup>†</sup>  |
|                                                                                                        | Estuarine and marine fish early life-stage NOAEC                 | No data                                                                                | NOAEC: 48 µg a.i./L                                         | No specific endpoint                                                                                                                                                             | Acute to Chronic Ratio <sup>†</sup>                                             |
| <u>Estuarine and marine invertebrates:</u><br>Survival and reproduction of individuals and communities | Estuarine and marine invertebrate acute EC <sub>50</sub><br>96-h | Eastern oyster ( <i>Crassostrea virginica</i> ) (shell deposition)<br><br>Flow-through | EC <sub>50</sub> : 490 µg a.i./L                            | --                                                                                                                                                                               | MRID 43393002<br><b>Acceptable</b><br><br><i>Highly toxic</i> <sup>†</sup>      |
|                                                                                                        |                                                                  | Mysid ( <i>Americamysis bahia</i> )<br><br>Flow-through                                | LC <sub>50</sub> : 0.04 µg a.i./L<br>NOAEC: 0.018 µg a.i./L | Lethality<br><br>NOAEC was based on 10% mortality at 0.026 µg a.i./L                                                                                                             | MRID 43393001<br><b>Acceptable</b><br><br><i>Very highly toxic</i> <sup>†</sup> |

| Assessment Endpoint                                    | Measures of Effect                                                                        | Species                                                                  | Toxicity Value*                                                                                                        | Study classification (Selection basis)                                             | Reference                                  |
|--------------------------------------------------------|-------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|--------------------------------------------|
|                                                        | Estuarine and marine invertebrate life cycle NOAEC                                        | Mysid <sup>4</sup><br>( <i>Americamysis bahia</i> )<br><br>Flow-through  | NOAEC: 0.0087 µg a.i./L<br>LOAEC: 0.013 µg a.i./L                                                                      | Reproduction; growth<br><br>Reduced growth                                         | MRID 45833001<br>Supplemental <sup>3</sup> |
| Aquatic plants:<br>Standing crop or biomass and growth | Non-vascular<br>Freshwater green algae, cyanobacteria or diatom EC <sub>50</sub><br>5-day | Freshwater green algae<br><i>Selenastrum capricornutum</i><br><br>Static | EC <sub>50</sub> > 3.9 µg a.i./L<br>NOAEC ≥ 3.9 µg a.i./L<br><br>*Values based on initial measured test concentrations | Cell density<br><br>A 13% reduction in algal growth was observed at 3.9 µg a.i./L. | MRID 43850108<br>Acceptable                |
|                                                        | Vascular<br>Freshwater EC <sub>50</sub><br>14-day                                         | Duckweed<br><i>Lemna gibba</i><br><br>Static                             | EC <sub>50</sub> > 94 µg a.i./L<br>NOAEC ≥ 94 µg a.i./L<br><br>*Values based on initial measured test concentrations   | Frond biomass                                                                      | MRID 43850109<br>Acceptable                |

<sup>1</sup> No chronic toxicity data available for estuarine/marine fish; therefore, chronic toxicity values estimated via acute to chronic ratio.

<sup>2</sup> An additional acute waterflea study was submitted (MRID 44007901) with an EC<sub>50</sub> > 728 µg a.i./L, presumably on a degradate of emamectin benzoate (see May 8, 1998 memo: D226628, D227718, D228127, D231325, D238388).

<sup>3</sup> Highly erratic test concentrations were observed throughout the study. Measurements were made of dissolved and sorbed material; thus, true dissolved concentrations and toxicity parameters may be lower than reported. Test concentrations decreased over time; as a result, mean-concentrations from days 1 to 14 and from days 15 to 28 were used to bracket the NOAECs. The 28-day mean measured NOAEC is reported. Also, as a result, had the exposure concentrations been maintained at a constant level during the entire 28-day study duration, effects may have occurred at or below the identified NOAEC.

<sup>4</sup> An additional chronic mysid study was submitted (MRID 44305601) with a NOAEC = 0.018 µg a.i./L (LOAEC of 0.028 µg a.i./L) also on the TGAI. Adult survival and length were adversely affected. However, the test concentrations varied considerably over the duration of the study and the study was also classified supplemental.

\*To convert µg a.i./L to mg a.i./L, multiply µg a.i./L value by 0.001.

<sup>†</sup> Based on EC<sub>50</sub> (mg/L): < 0.1 very highly toxic; 0.1-1 highly toxic; >1-10 moderately toxic; >10-100 slightly toxic; >100 practically nontoxic.



## APPENDIX 2. Summary of Environmental Fate Data and Model Input Parameters for Emamectin Benzoate.

### Environmental Fate Characterization

Based on acceptable and supplemental data, emamectin benzoate is not persistent in aerobic environments, but is persistent in anaerobic environments. Emamectin benzoate is also stable to hydrolysis, but is not persistent in photolysis studies. The compound is also considered a systemic insecticide that is stable within the plant matter (USEPA 1994). A summary of the environmental fate properties may be found in Table 5 below.

**Fate Properties and Model Input Parameters for Emamectin Benzoate**

| Property                               | Value                                                                                                              | Reference                                                                                                                                                                                                                                                                                                                                          |
|----------------------------------------|--------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Molecular Weight                       | 964                                                                                                                | New Chemical Review (D226628, 2000)                                                                                                                                                                                                                                                                                                                |
| CAS number                             | Emamectin: 148477-71-8 (formerly 123997-28-4), Emamectin Benzoate: 155569-91-8 (formerly 137512-74-4, 179607-18-2) | New Chemical Review (D226628, 2000), <a href="http://www.alanwood.net/pesticides/derivatives/emamectin%20benzoate.html">http://www.alanwood.net/pesticides/derivatives/emamectin%20benzoate.html</a> , <a href="http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?/temp/~I9D6iR:1">http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?/temp/~I9D6iR:1</a> |
| Water solubility; (pH 7)               | 93 mg/L                                                                                                            | Product Chemistry; MRID 44883704;                                                                                                                                                                                                                                                                                                                  |
| Vapor pressure                         | $3 \times 10^{-8}$ Torr                                                                                            | New Chemical Review (D226628, 2000); (25°C)                                                                                                                                                                                                                                                                                                        |
| log $K_{ow}$                           | 5.0 (pH 7)                                                                                                         | New Chemical Review (D226628, 2000)                                                                                                                                                                                                                                                                                                                |
| Henry's law constant                   | $3.8 \times 10^{-10}$ atm m <sup>3</sup> /mol                                                                      | Product Chemistry; MRID 44883705                                                                                                                                                                                                                                                                                                                   |
| Hydrolysis half-life                   | $t_{1/2}$ = Stable                                                                                                 | MRID 42743642; (pH 7)                                                                                                                                                                                                                                                                                                                              |
| Aqueous photolysis half-life           | $t_{1/2}$ = 23 days                                                                                                | MRID 43850114 (natural sunlight - maximum value)                                                                                                                                                                                                                                                                                                   |
| Soil photolysis half-life              | $t_{1/2}$ = 5 days                                                                                                 | MRID 43404302; (uncorrected for dark controls)                                                                                                                                                                                                                                                                                                     |
| Aerobic soil metabolism half-life      | $t_{1/2}$ = 107.5 days                                                                                             | MRID 43404303 (193.4), 48480101 (75.3, 78.8), 48480102 (60.8, 35.9), 48480103 (57.8, 50.2); per Input Parameter Guidance.                                                                                                                                                                                                                          |
| Anaerobic aquatic metabolism half-life | $t_{1/2}$ = 1281 days                                                                                              | MRID 43850116 (Anaerobic soil half-life value: 427 days x 3 = 1281 days); per Input Parameter Guidance.                                                                                                                                                                                                                                            |
| Aerobic aquatic metabolism half-life   | $t_{1/2}$ = 215 days                                                                                               | Aerobic soil half-life value: 107.5 times 2 per Input Parameter Guidance.                                                                                                                                                                                                                                                                          |
| Adsorption coefficient $K_{oc}$        | 265,687 (average)                                                                                                  | MRID 428515-26; $K_{oc}$ = 279,000 - 730,000 - 25,382 - 28,365)                                                                                                                                                                                                                                                                                    |
| Bioconcentration factor (BCF)          | 69                                                                                                                 | MRID 434930-05; (whole fish)                                                                                                                                                                                                                                                                                                                       |



Emamectin benzoate consists of a mixture of at least 90% 4"-epi-methylamino-4"-deoxyavermectin B<sub>1a</sub> and a maximum of 10% 4"-epi-methylamino-4"-deoxyavermectin B<sub>1b</sub> benzoate. The available chemical properties and environmental fate data are primarily on the B<sub>1a</sub> component; therefore, there is some uncertainty on the fate of the B<sub>1b</sub> component. However, both components have very similar structures; therefore, their physicochemical properties, fate, and toxicity profiles are assumed to be similar. Some of emamectin benzoate's properties are pH dependent. For example, its water solubility is 320 mg/L at pH 5, 93 mg/L at pH 7, and 0.1 mg/L at pH 9. Similarly, its log K<sub>ow</sub> is 5.0 at pH 7 and 5.9 at pH 9. Therefore, its properties may be altered by pH. Emamectin benzoate's low vapor pressure and Henry's law constant suggest that volatility from soil and water, respectively, will be low.

The Agency has identified four degradates of concern based on structural similarity to emamectin benzoate that are formed via photolysis:

- (8,9-Z)-4"-epimethylamino-4"-deoxy avermectin B1 (8,9 ZMA isomer);
- 4"-epiamino-4"-deoxyavermectin B1 (AB);
- avermectin B1 monosaccharide (MAB); and
- 4"-epi-(N-formyl)-4"-deoxyavermectin B1 (FAB)

These degradates will be included in the risk assessment for emamectin benzoate and are assumed to be of equal toxicity to the parent compound. The total toxic residues approach will be used for determining the Environmental fate data parameters for modeling using the *Guidance for Selecting Input Parameters in Modeling the Environmental Fate and Transport of Pesticides*, Version 2.1, October 22, 2009 and the draft *Guidance for Modeling Pesticides Total Toxic Residues (TTR)* May 20, 2009.

Half-lives for the total residues of toxicological concern are calculated by adding the residues of the parent compound, with residues from the degradates of concern (in terms of percent of the applied radiation) for each sampling interval. These totals are converted into natural logs, and plotted against time. The slope of the regression line from that plot is used to calculate the new half-life ( $\ln(2)/k$ ; when  $k$  is the slope of the regression line).

**Terrestrial Environments.** Mobility studies conducted with emamectin benzoate indicate that the parent compound and its degradates would be expected to be relatively immobile in the environment due to a high degree of sorption to soil particles ( $K_d$  219 to 2037). Therefore, most of the emamectin benzoate that enters the terrestrial environment is expected to remain at the site of application until it degrades or is transported via soil erosion. For this reason, high levels of parent and/or transformation products are not expected to enter surface water through runoff or to leach into ground water. The low emamectin benzoate vapor pressure suggests that volatilization from soil is expected to be minimal. Emamectin benzoate is resistant to microbial degradation (half-life 193 days) and hydrolysis (stable), and is expected to be persistent when it is attenuated from light. The primary environmental dissipation pathway of emamectin benzoate is expected to be through photolysis on soil (half-life 5 days); however, degradation within injected trees has not been evaluated.

**Aqueous Environments.** Enamectin benzoate is expected to enter the water primarily through soil erosion or treated materials falling into bodies of water. Once in an aquatic system, emamectin benzoate is likely to remain bound to sediment or suspended particles. It does not hydrolyze in water at pH 5 to 8, but slowly hydrolyzes at pH 9 (half-life 20 weeks). Its low Henry's Law constant suggests that volatilization from water is likely to be negligible. Although emamectin benzoate degrades rapidly through aqueous photolysis, other than in oligotrophic systems (clear, shallow water bodies with low in organic matter content), aqueous photolysis is not likely to significantly contribute to the degradation of emamectin benzoate. Although emamectin benzoate appears to not be expected to bioconcentrate to any appreciable extent (whole fish BCF = 69), the  $K_{ow}$  ( $\log K_{ow} > 5$ ) suggests the potential for bioaccumulation.



### APPENDIX 3.

#### Risk Characterization

Risk characterization integrates EECs and toxicity estimates to determine whether the proposed emamectin uses pose risk to non-target species at levels of concern to the Agency. In a deterministic approach, a single point estimate of toxicity is divided by an exposure estimate to calculate a risk quotient (RQ). The RQ is then compared to Agency LOCs, which serve as criteria for categorizing potential risk to non-target organisms. LOCs currently address the following risk presumption categories:

#### Risk presumptions for terrestrial animals

| Risk Presumption         | Risk Quotient (RQ)                                  | Level of Concern (LOC) |
|--------------------------|-----------------------------------------------------|------------------------|
| <b>Birds</b>             |                                                     |                        |
| Acute Risk               | EEC <sup>1</sup> /LC <sub>50</sub>                  | 0.5                    |
| Acute Restricted Use     | EEC/LC <sub>50</sub> or LD <sub>50</sub> < 50 mg/kg | 0.2                    |
| Acute Endangered Species | EEC/LC <sub>50</sub>                                | 0.1                    |
| Chronic Risk             | EEC/NOAEC                                           | 1                      |
| <b>Wild Mammals</b>      |                                                     |                        |
| Acute Risk               | EEC/LC <sub>50</sub>                                | 0.5                    |
| Acute Restricted Use     | EEC/LC <sub>50</sub> or LD <sub>50</sub> < 50 mg/kg | 0.2                    |
| Acute Endangered Species | EEC/LC <sub>50</sub>                                | 0.1                    |
| Chronic Risk             | EEC/NOAEC                                           | 1                      |

<sup>1</sup> abbreviation for Estimated Environmental Concentration (ppm) on avian/mammalian food items

#### Risk presumptions for aquatic animals

| Risk Presumption         | RQ                                                     | LOC  |
|--------------------------|--------------------------------------------------------|------|
| Acute Risk               | EEC <sup>1</sup> /LC <sub>50</sub> or EC <sub>50</sub> | 0.5  |
| Acute Restricted Use     | EEC/LC <sub>50</sub> or EC <sub>50</sub>               | 0.1  |
| Acute Endangered Species | EEC/LC <sub>50</sub> or EC <sub>50</sub>               | 0.05 |
| Chronic Risk             | EEC/NOAEC                                              | 1    |

<sup>1</sup> EEC = (ppm or ppb) in water



## Risk presumptions for plants

| Risk Presumption                                           | RQ                                 | LOC |
|------------------------------------------------------------|------------------------------------|-----|
| <b>Plant Inhabiting Terrestrial and Semi-Aquatic Areas</b> |                                    |     |
| Acute Risk                                                 | EEC <sup>1</sup> /EC <sub>25</sub> | 1   |
| Acute Endangered Species                                   | EEC/EC <sub>05</sub> or NOAEC      | 1   |
| <b>Aquatic Plants</b>                                      |                                    |     |
| Acute Risk                                                 | EEC <sup>2</sup> /EC <sub>20</sub> | 1   |
| Acute Endangered Species                                   | EEC/EC <sub>05</sub> or NOAEC      | 1   |

<sup>1</sup> EEC = lbs.a.i./A ; <sup>2</sup> EEC = (ppb or ppm) in water

The risk estimation presents risk quotients calculated for emamectin and the LOCs (if any) that are exceeded. Further discussion of the risk quotients and uncertainties in the assessment is presented in the risk description for each taxa assessed.

## APPENDIX 4.

### PRZM/EXAMS output files

#### Outdoor Ornamentals:

stored as CANursery.out

Chemical: emamectin benzoate

PRZM environment: CANurserySTD.txt

modified Tuesday, 26 August 2008 at 05:16:36

EXAMS environment: pond298.exv

modified Tuesday, 26 August 2008 at 05:14:08

Metfile: w23188.dvf modified Tuesday, 26 August 2008 at 05:15:38

Water segment concentrations (ppb)

| Year | Peak    | 96 hr   | 21 Day   | 60 Day   | 90 Day   | Yearly    |
|------|---------|---------|----------|----------|----------|-----------|
| 1961 | 0.0631  | 0.01719 | 0.004988 | 0.002325 | 0.001674 | 0.0006751 |
| 1962 | 0.1129  | 0.03609 | 0.01144  | 0.0083   | 0.007734 | 0.006331  |
| 1963 | 0.1191  | 0.03743 | 0.0157   | 0.01148  | 0.01025  | 0.007758  |
| 1964 | 0.0432  | 0.01898 | 0.01203  | 0.01131  | 0.01113  | 0.01077   |
| 1965 | 0.1432  | 0.06403 | 0.03192  | 0.02426  | 0.02047  | 0.01488   |
| 1966 | 0.152   | 0.06187 | 0.03278  | 0.02617  | 0.02501  | 0.02191   |
| 1967 | 0.1218  | 0.05469 | 0.03386  | 0.02995  | 0.02827  | 0.02693   |
| 1968 | 0.04515 | 0.03271 | 0.02933  | 0.02925  | 0.02897  | 0.02776   |
| 1969 | 0.2024  | 0.07305 | 0.03976  | 0.03507  | 0.03399  | 0.03107   |
| 1970 | 0.1213  | 0.05413 | 0.03684  | 0.0336   | 0.03307  | 0.03145   |
| 1971 | 0.07575 | 0.0478  | 0.03564  | 0.03428  | 0.03413  | 0.03312   |
| 1972 | 0.1183  | 0.05831 | 0.04052  | 0.03635  | 0.03435  | 0.03274   |
| 1973 | 0.05673 | 0.03823 | 0.03472  | 0.0346   | 0.0345   | 0.03335   |
| 1974 | 0.2121  | 0.08071 | 0.04572  | 0.03817  | 0.03675  | 0.03539   |
| 1975 | 0.08127 | 0.04871 | 0.04103  | 0.04004  | 0.03959  | 0.03755   |
| 1976 | 0.1397  | 0.06968 | 0.04621  | 0.0416   | 0.04124  | 0.03877   |
| 1977 | 0.4261  | 0.1417  | 0.06595  | 0.05389  | 0.05149  | 0.04598   |
| 1978 | 0.1495  | 0.07147 | 0.04949  | 0.0473   | 0.04703  | 0.04529   |
| 1979 | 0.09121 | 0.06278 | 0.05002  | 0.04902  | 0.04844  | 0.04585   |
| 1980 | 0.1334  | 0.07136 | 0.05376  | 0.05091  | 0.04995  | 0.04674   |
| 1981 | 0.2018  | 0.08374 | 0.05224  | 0.04653  | 0.046    | 0.04414   |
| 1982 | 0.1047  | 0.05904 | 0.04933  | 0.04761  | 0.04694  | 0.04516   |
| 1983 | 0.09967 | 0.05894 | 0.04985  | 0.04825  | 0.04784  | 0.04508   |
| 1984 | 0.1362  | 0.06551 | 0.04826  | 0.04207  | 0.04185  | 0.04067   |
| 1985 | 0.2481  | 0.094   | 0.06006  | 0.04994  | 0.04604  | 0.04202   |
| 1986 | 0.1383  | 0.07033 | 0.05215  | 0.05016  | 0.04944  | 0.04661   |
| 1987 | 0.1304  | 0.06979 | 0.05414  | 0.05112  | 0.04948  | 0.04797   |
| 1988 | 0.1801  | 0.1054  | 0.06513  | 0.05808  | 0.05659  | 0.05273   |
| 1989 | 0.1288  | 0.06829 | 0.0518   | 0.05156  | 0.05141  | 0.04959   |
| 1990 | 0.08393 | 0.05836 | 0.05096  | 0.04991  | 0.04962  | 0.04747   |

#### Sorted results

| Prob.              | Peak   | 96 hr   | 21 Day  | 60 Day  | 90 Day  | Yearly  |
|--------------------|--------|---------|---------|---------|---------|---------|
| 0.032258064516129  | 0.4261 | 0.1417  | 0.06595 | 0.05808 | 0.05659 | 0.05273 |
| 0.0645161290322581 | 0.2481 | 0.1054  | 0.06513 | 0.05389 | 0.05149 | 0.04959 |
| 0.0967741935483871 | 0.2121 | 0.094   | 0.06006 | 0.05156 | 0.05141 | 0.04797 |
| 0.129032258064516  | 0.2024 | 0.08374 | 0.05414 | 0.05112 | 0.04995 | 0.04747 |
| 0.161290322580645  | 0.2018 | 0.08071 | 0.05376 | 0.05091 | 0.04962 | 0.04674 |
| 0.193548387096774  | 0.1801 | 0.07305 | 0.05224 | 0.05016 | 0.04948 | 0.04661 |
| 0.225806451612903  | 0.152  | 0.07147 | 0.05215 | 0.04994 | 0.04944 | 0.04598 |
| 0.258064516129032  | 0.1495 | 0.07136 | 0.0518  | 0.04991 | 0.04844 | 0.04585 |
| 0.290322580645161  | 0.1432 | 0.07033 | 0.05096 | 0.04902 | 0.04784 | 0.04529 |
| 0.32258064516129   | 0.1397 | 0.06979 | 0.05002 | 0.04825 | 0.04703 | 0.04516 |
| 0.354838709677419  | 0.1383 | 0.06968 | 0.04985 | 0.04761 | 0.04694 | 0.04508 |
| 0.387096774193548  | 0.1362 | 0.06829 | 0.04949 | 0.0473  | 0.04604 | 0.04414 |
| 0.419354838709677  | 0.1334 | 0.06551 | 0.04933 | 0.04653 | 0.046   | 0.04202 |
| 0.451612903225806  | 0.1304 | 0.06403 | 0.04826 | 0.04207 | 0.04185 | 0.04067 |
| 0.483870967741936  | 0.1288 | 0.06278 | 0.04621 | 0.0416  | 0.04124 | 0.03877 |
| 0.516129032258065  | 0.1218 | 0.06187 | 0.04572 | 0.04004 | 0.03959 | 0.03755 |
| 0.548387096774194  | 0.1213 | 0.05904 | 0.04103 | 0.03817 | 0.03675 | 0.03539 |
| 0.580645161290323  | 0.1191 | 0.05894 | 0.04052 | 0.03635 | 0.0345  | 0.03335 |
| 0.612903225806452  | 0.1183 | 0.05836 | 0.03976 | 0.03507 | 0.03435 | 0.03312 |

|                   |         |         |          |          |          |           |
|-------------------|---------|---------|----------|----------|----------|-----------|
| 0.645161290322581 | 0.1129  | 0.05831 | 0.03684  | 0.0346   | 0.03413  | 0.03274   |
| 0.67741935483871  | 0.1047  | 0.05469 | 0.03564  | 0.03428  | 0.03399  | 0.03145   |
| 0.709677419354839 | 0.09967 | 0.05413 | 0.03472  | 0.0336   | 0.03307  | 0.03107   |
| 0.741935483870968 | 0.09121 | 0.04871 | 0.03386  | 0.02995  | 0.02897  | 0.02776   |
| 0.774193548387097 | 0.08393 | 0.0478  | 0.03278  | 0.02925  | 0.02827  | 0.02693   |
| 0.806451612903226 | 0.08127 | 0.03823 | 0.03192  | 0.02617  | 0.02501  | 0.02191   |
| 0.838709677419355 | 0.07575 | 0.03743 | 0.02933  | 0.02426  | 0.02047  | 0.01488   |
| 0.870967741935484 | 0.0631  | 0.03609 | 0.0157   | 0.01148  | 0.01113  | 0.01077   |
| 0.903225806451613 | 0.05673 | 0.03271 | 0.01203  | 0.01131  | 0.01025  | 0.007758  |
| 0.935483870967742 | 0.04515 | 0.01898 | 0.01144  | 0.0083   | 0.007734 | 0.006331  |
| 0.967741935483871 | 0.0432  | 0.01719 | 0.004988 | 0.002325 | 0.001674 | 0.0006751 |

0.1      0.21113    0.092974    0.059468    0.051516    0.051264    0.04792

Average of yearly averages:      0.0345251366666667

Inputs generated by pe5.pl - November 2006

Data used for this run:

Output File: CANursery

Metfile: w23188.dvf

PRZM scenario: CANurserySTD.txt

EXAMS environment file: pond298.exv

Chemical Name: emamectin benzoate

| Description | Variable Name | Value | Units | Comments |
|-------------|---------------|-------|-------|----------|
|-------------|---------------|-------|-------|----------|

|                  |     |        |       |  |
|------------------|-----|--------|-------|--|
| Molecular weight | mwt | 964.23 | g/mol |  |
|------------------|-----|--------|-------|--|

|                    |       |         |                         |  |
|--------------------|-------|---------|-------------------------|--|
| Henry's Law Const. | henry | 3.8e-10 | atm-m <sup>3</sup> /mol |  |
|--------------------|-------|---------|-------------------------|--|

|                |      |  |      |  |
|----------------|------|--|------|--|
| Vapor Pressure | vapr |  | torr |  |
|----------------|------|--|------|--|

|            |     |    |      |  |
|------------|-----|----|------|--|
| Solubility | sol | 93 | mg/L |  |
|------------|-----|----|------|--|

|    |    |  |      |  |
|----|----|--|------|--|
| Kd | Kd |  | mg/L |  |
|----|----|--|------|--|

|     |     |        |      |  |
|-----|-----|--------|------|--|
| Koc | Koc | 265687 | mg/L |  |
|-----|-----|--------|------|--|

|                      |     |    |      |           |
|----------------------|-----|----|------|-----------|
| Photolysis half-life | kdp | 23 | days | Half-life |
|----------------------|-----|----|------|-----------|

|                            |       |     |      |         |
|----------------------------|-------|-----|------|---------|
| Aerobic Aquatic Metabolism | kbacw | 215 | days | Halfife |
|----------------------------|-------|-----|------|---------|

|                              |       |      |      |         |
|------------------------------|-------|------|------|---------|
| Anaerobic Aquatic Metabolism | kbacs | 1281 | days | Halfife |
|------------------------------|-------|------|------|---------|

|                         |     |       |      |         |
|-------------------------|-----|-------|------|---------|
| Aerobic Soil Metabolism | asm | 107.5 | days | Halfife |
|-------------------------|-----|-------|------|---------|

|             |      |   |      |           |
|-------------|------|---|------|-----------|
| Hydrolysis: | pH 5 | 0 | days | Half-life |
|-------------|------|---|------|-----------|

|             |      |   |      |           |
|-------------|------|---|------|-----------|
| Hydrolysis: | pH 7 | 0 | days | Half-life |
|-------------|------|---|------|-----------|

|             |      |   |      |           |
|-------------|------|---|------|-----------|
| Hydrolysis: | pH 9 | 0 | days | Half-life |
|-------------|------|---|------|-----------|

|         |     |   |         |                 |
|---------|-----|---|---------|-----------------|
| Method: | CAM | 2 | integer | See PRZM manual |
|---------|-----|---|---------|-----------------|

|                      |      |   |    |  |
|----------------------|------|---|----|--|
| Incorporation Depth: | DEPI | 0 | cm |  |
|----------------------|------|---|----|--|

|                   |      |       |       |  |
|-------------------|------|-------|-------|--|
| Application Rate: | TAPP | 0.017 | kg/ha |  |
|-------------------|------|-------|-------|--|

|                         |        |      |          |  |
|-------------------------|--------|------|----------|--|
| Application Efficiency: | APPEFF | 0.99 | fraction |  |
|-------------------------|--------|------|----------|--|

|             |      |      |                                              |  |
|-------------|------|------|----------------------------------------------|--|
| Spray Drift | DRFT | 0.01 | fraction of application rate applied to pond |  |
|-------------|------|------|----------------------------------------------|--|

|                  |      |     |                                   |  |
|------------------|------|-----|-----------------------------------|--|
| Application Date | Date | 1-4 | dd/mm or dd/mm or dd-mm or dd-mmm |  |
|------------------|------|-----|-----------------------------------|--|

|                     |   |      |                                         |  |
|---------------------|---|------|-----------------------------------------|--|
| Interval 1 interval | 7 | days | Set to 0 or delete line for single app. |  |
|---------------------|---|------|-----------------------------------------|--|

|                     |       |       |  |  |
|---------------------|-------|-------|--|--|
| app. rate 1 apprate | 0.017 | kg/ha |  |  |
|---------------------|-------|-------|--|--|

|                     |   |      |                                         |  |
|---------------------|---|------|-----------------------------------------|--|
| Interval 2 interval | 7 | days | Set to 0 or delete line for single app. |  |
|---------------------|---|------|-----------------------------------------|--|

|                     |       |       |  |  |
|---------------------|-------|-------|--|--|
| app. rate 2 apprate | 0.017 | kg/ha |  |  |
|---------------------|-------|-------|--|--|

|                     |   |      |                                         |  |
|---------------------|---|------|-----------------------------------------|--|
| Interval 3 interval | 7 | days | Set to 0 or delete line for single app. |  |
|---------------------|---|------|-----------------------------------------|--|

|                     |       |       |  |  |
|---------------------|-------|-------|--|--|
| app. rate 3 apprate | 0.017 | kg/ha |  |  |
|---------------------|-------|-------|--|--|

|                     |   |      |                                         |  |
|---------------------|---|------|-----------------------------------------|--|
| Interval 4 interval | 7 | days | Set to 0 or delete line for single app. |  |
|---------------------|---|------|-----------------------------------------|--|

|                     |       |       |  |  |
|---------------------|-------|-------|--|--|
| app. rate 4 apprate | 0.017 | kg/ha |  |  |
|---------------------|-------|-------|--|--|

|                     |   |      |                                         |  |
|---------------------|---|------|-----------------------------------------|--|
| Interval 5 interval | 7 | days | Set to 0 or delete line for single app. |  |
|---------------------|---|------|-----------------------------------------|--|

|                     |       |       |  |  |
|---------------------|-------|-------|--|--|
| app. rate 5 apprate | 0.017 | kg/ha |  |  |
|---------------------|-------|-------|--|--|

Record 17: FILTRA

IPSCND 1

UPTKF

Record 18: PLVKRT

PLDKRT

FEXTRC 0.5

|                         |    |          |
|-------------------------|----|----------|
| Flag for Index Res. Run | IR | EPA Pond |
|-------------------------|----|----------|

|                       |        |                                               |
|-----------------------|--------|-----------------------------------------------|
| Flag for runoff calc. | RUNOFF | none, monthly or total(average of entire run) |
|-----------------------|--------|-----------------------------------------------|

stored as FLNursery.out

Chemical: emamectin benzoate

PRZM environment: FLNurserySTD.txt      modified Tuesday, 26 August 2008 at 05:16:38

EXAMS environment: pond298.exv      modified Tuesday, 26 August 2008 at 05:14:08

Metfile: w12839.dvf      modified Tuesday, 26 August 2008 at 05:14:20

Water segment concentrations (ppb)



| Year | Peak    | 96 hr    | 21 Day   | 60 Day   | 90 Day   | Yearly   |
|------|---------|----------|----------|----------|----------|----------|
| 1961 | 0.02529 | 0.008815 | 0.004156 | 0.003208 | 0.003072 | 0.001975 |
| 1962 | 0.02035 | 0.009917 | 0.006138 | 0.005495 | 0.005333 | 0.004154 |
| 1963 | 0.03012 | 0.01273  | 0.008099 | 0.007103 | 0.006874 | 0.006059 |
| 1964 | 0.06212 | 0.02223  | 0.01168  | 0.01018  | 0.009951 | 0.008217 |
| 1965 | 0.0457  | 0.02077  | 0.01287  | 0.01217  | 0.01184  | 0.01032  |
| 1966 | 0.04472 | 0.0261   | 0.01612  | 0.01532  | 0.01499  | 0.0135   |
| 1967 | 0.05552 | 0.02943  | 0.01839  | 0.01664  | 0.01615  | 0.01493  |
| 1968 | 0.0473  | 0.02479  | 0.0202   | 0.01973  | 0.0193   | 0.01735  |
| 1969 | 0.03186 | 0.02142  | 0.01918  | 0.01871  | 0.0186   | 0.018    |
| 1970 | 0.04962 | 0.02634  | 0.02107  | 0.01919  | 0.01869  | 0.01783  |
| 1971 | 0.03628 | 0.0234   | 0.01924  | 0.01807  | 0.018    | 0.01726  |
| 1972 | 0.05639 | 0.02935  | 0.02039  | 0.01939  | 0.01914  | 0.01775  |
| 1973 | 0.0359  | 0.02248  | 0.01961  | 0.01815  | 0.01779  | 0.01722  |
| 1974 | 0.05047 | 0.0257   | 0.01847  | 0.01739  | 0.01738  | 0.01672  |
| 1975 | 0.02366 | 0.0176   | 0.01669  | 0.01644  | 0.01619  | 0.0155   |
| 1976 | 0.04117 | 0.02241  | 0.01717  | 0.01622  | 0.01609  | 0.01541  |
| 1977 | 0.1335  | 0.04625  | 0.02341  | 0.02111  | 0.02027  | 0.0176   |
| 1978 | 0.02481 | 0.01965  | 0.01807  | 0.01787  | 0.01769  | 0.01676  |
| 1979 | 0.1443  | 0.04934  | 0.02417  | 0.0204   | 0.01972  | 0.01758  |
| 1980 | 0.04617 | 0.02518  | 0.02037  | 0.01936  | 0.01912  | 0.01832  |
| 1981 | 0.0464  | 0.0297   | 0.02084  | 0.02001  | 0.01951  | 0.01838  |
| 1982 | 0.07169 | 0.03235  | 0.0219   | 0.02081  | 0.02052  | 0.01904  |
| 1983 | 0.03586 | 0.02465  | 0.01978  | 0.01932  | 0.01909  | 0.01852  |
| 1984 | 0.05939 | 0.03274  | 0.02239  | 0.02074  | 0.02041  | 0.01906  |
| 1985 | 0.0406  | 0.02644  | 0.02276  | 0.02129  | 0.02099  | 0.01932  |
| 1986 | 0.04619 | 0.02804  | 0.02213  | 0.02113  | 0.02093  | 0.01988  |
| 1987 | 0.04574 | 0.02513  | 0.02002  | 0.01917  | 0.01897  | 0.01843  |
| 1988 | 0.03472 | 0.023    | 0.01984  | 0.0189   | 0.01881  | 0.01783  |
| 1989 | 0.03908 | 0.02301  | 0.01945  | 0.0182   | 0.0179   | 0.01709  |
| 1990 | 0.04938 | 0.02498  | 0.01944  | 0.01829  | 0.01824  | 0.01747  |

#### Sorted results

| Prob.              | Peak    | 96 hr    | 21 Day   | 60 Day   | 90 Day   | Yearly   |
|--------------------|---------|----------|----------|----------|----------|----------|
| 0.032258064516129  | 0.1443  | 0.04934  | 0.02417  | 0.02129  | 0.02099  | 0.01988  |
| 0.0645161290322581 | 0.1335  | 0.04625  | 0.02341  | 0.02113  | 0.02093  | 0.01932  |
| 0.0967741935483871 | 0.07169 | 0.03274  | 0.02276  | 0.02111  | 0.02052  | 0.01906  |
| 0.129032258064516  | 0.06212 | 0.03235  | 0.02239  | 0.02081  | 0.02041  | 0.01904  |
| 0.161290322580645  | 0.05939 | 0.0297   | 0.02213  | 0.02074  | 0.02027  | 0.01852  |
| 0.193548387096774  | 0.05639 | 0.02943  | 0.0219   | 0.0204   | 0.01972  | 0.01843  |
| 0.225806451612903  | 0.05552 | 0.02935  | 0.02107  | 0.02001  | 0.01951  | 0.01838  |
| 0.258064516129032  | 0.05047 | 0.02804  | 0.02084  | 0.01973  | 0.0193   | 0.01832  |
| 0.290322580645161  | 0.04962 | 0.02644  | 0.02039  | 0.01939  | 0.01914  | 0.018    |
| 0.32258064516129   | 0.04938 | 0.02634  | 0.02037  | 0.01936  | 0.01912  | 0.01783  |
| 0.354838709677419  | 0.0473  | 0.0261   | 0.0202   | 0.01932  | 0.01909  | 0.01783  |
| 0.387096774193548  | 0.0464  | 0.0257   | 0.02002  | 0.01919  | 0.01897  | 0.01775  |
| 0.419354838709677  | 0.04619 | 0.02518  | 0.01984  | 0.01917  | 0.01881  | 0.0176   |
| 0.451612903225806  | 0.04617 | 0.02513  | 0.01978  | 0.0189   | 0.01869  | 0.01758  |
| 0.483870967741936  | 0.04574 | 0.02498  | 0.01961  | 0.01871  | 0.0186   | 0.01747  |
| 0.516129032258065  | 0.0457  | 0.02479  | 0.01945  | 0.01829  | 0.01824  | 0.01735  |
| 0.548387096774194  | 0.04472 | 0.02465  | 0.01944  | 0.0182   | 0.018    | 0.01726  |
| 0.580645161290323  | 0.04117 | 0.0234   | 0.01924  | 0.01815  | 0.0179   | 0.01722  |
| 0.612903225806452  | 0.0406  | 0.02301  | 0.01918  | 0.01807  | 0.01779  | 0.01709  |
| 0.645161290322581  | 0.03908 | 0.023    | 0.01847  | 0.01787  | 0.01769  | 0.01676  |
| 0.67741935483871   | 0.03628 | 0.02248  | 0.01839  | 0.01739  | 0.01738  | 0.01672  |
| 0.709677419354839  | 0.0359  | 0.02241  | 0.01807  | 0.01664  | 0.01619  | 0.0155   |
| 0.741935483870968  | 0.03586 | 0.02223  | 0.01717  | 0.01644  | 0.01615  | 0.01541  |
| 0.774193548387097  | 0.03472 | 0.02142  | 0.01669  | 0.01622  | 0.01609  | 0.01493  |
| 0.806451612903226  | 0.03186 | 0.02077  | 0.01612  | 0.01532  | 0.01499  | 0.0135   |
| 0.838709677419355  | 0.03012 | 0.01965  | 0.01287  | 0.01217  | 0.01184  | 0.01032  |
| 0.870967741935484  | 0.02529 | 0.0176   | 0.01168  | 0.01018  | 0.009951 | 0.008217 |
| 0.903225806451613  | 0.02481 | 0.01273  | 0.008099 | 0.007103 | 0.006874 | 0.006059 |
| 0.935483870967742  | 0.02366 | 0.009917 | 0.006138 | 0.005495 | 0.005333 | 0.004154 |
| 0.967741935483871  | 0.02035 | 0.008815 | 0.004156 | 0.003208 | 0.003072 | 0.001975 |

0.1      0.070733   0.032701   0.022723   0.02108   0.020509   0.019058  
Average of yearly averages:      0.0155825

Inputs generated by pe5.pl - November 2006

Data used for this run:

Output File: FLNursery

Metfile: w12839.dvf

PRZM scenario: FLNurserySTD.txt

EXAMS environment file: pond298.exv

Chemical Name: emamectin benzoate

| Description                  | Variable Name | Value   | Units                                         | Comments                                |
|------------------------------|---------------|---------|-----------------------------------------------|-----------------------------------------|
| Molecular weight             | mwt           | 964.23  | g/mol                                         |                                         |
| Henry's Law Const.           | henry         | 3.8e-10 | atm-m <sup>3</sup> /mol                       |                                         |
| Vapor Pressure               | vapr          |         | torr                                          |                                         |
| Solubility sol               | 93            | mg/L    |                                               |                                         |
| Kd                           | Kd            | mg/L    |                                               |                                         |
| Koc                          | Koc           | 265687  | mg/L                                          |                                         |
| Photolysis half-life         | kdp           | 23      | days                                          | Half-life                               |
| Aerobic Aquatic Metabolism   | kbacw         | 215     | days                                          | Halfife                                 |
| Anaerobic Aquatic Metabolism | kbacs         | 1281    | days                                          | Halfife                                 |
| Aerobic Soil Metabolism      | asm           | 107.5   | days                                          | Halfife                                 |
| Hydrolysis:                  | pH 5          | 0       | days                                          | Half-life                               |
| Hydrolysis:                  | pH 7          | 0       | days                                          | Half-life                               |
| Hydrolysis:                  | pH 9          | 0       | days                                          | Half-life                               |
| Method:                      | CAM 2         | integer |                                               | See PRZM manual                         |
| Incorporation Depth:         | DEPI          | 0       | cm                                            |                                         |
| Application Rate:            | TAPP          | 0.017   | kg/ha                                         |                                         |
| Application Efficiency:      | APPEFF        | 0.99    | fraction                                      |                                         |
| Spray Drift                  | DRFT          | 0.01    | fraction of application rate applied to pond  |                                         |
| Application Date             | Date          | 2-1     | dd/mm or dd/mm or dd-mm or dd-mmm             |                                         |
| Interval 1 interval          | 7             | days    |                                               | Set to 0 or delete line for single app. |
| app. rate 1 apprate          | 0.017         | kg/ha   |                                               |                                         |
| Interval 2 interval          | 7             | days    |                                               | Set to 0 or delete line for single app. |
| app. rate 2 apprate          | 0.017         | kg/ha   |                                               |                                         |
| Interval 3 interval          | 7             | days    |                                               | Set to 0 or delete line for single app. |
| app. rate 3 apprate          | 0.017         | kg/ha   |                                               |                                         |
| Interval 4 interval          | 7             | days    |                                               | Set to 0 or delete line for single app. |
| app. rate 4 apprate          | 0.017         | kg/ha   |                                               |                                         |
| Interval 5 interval          | 7             | days    |                                               | Set to 0 or delete line for single app. |
| app. rate 5 apprate          | 0.017         | kg/ha   |                                               |                                         |
| Record 17: FILTRA            |               |         |                                               |                                         |
| IPSCND                       | 1             |         |                                               |                                         |
| UPTKF                        |               |         |                                               |                                         |
| Record 18: PLVKRT            |               |         |                                               |                                         |
| PLDKRT                       |               |         |                                               |                                         |
| FEXTRC                       | 0.5           |         |                                               |                                         |
| Flag for Index Res. Run      | IR            |         | EPA Pond                                      |                                         |
| Flag for runoff calc.        | RUNOFF        | none    | none, monthly or total(average of entire run) |                                         |

stored as MINursery.out

Chemical: emamectin benzoate

PRZM environment: MINurserySTD.txt

modified Tuesday, 26 August 2008 at 05:16:40

EXAMS environment: pond298.exv

modified Tuesday, 26 August 2008 at 05:14:08

Metfile: w14840.dvf modified Tuesday, 26 August 2008 at 05:15:06

Water segment concentrations (ppb)

| Year | Peak    | 96 hr    | 21 Day   | 60 Day   | 90 Day   | Yearly   |
|------|---------|----------|----------|----------|----------|----------|
| 1961 | 0.01295 | 0.004784 | 0.002825 | 0.002402 | 0.002322 | 0.001574 |
| 1962 | 0.01527 | 0.006695 | 0.004408 | 0.004071 | 0.003997 | 0.003408 |
| 1963 | 0.01744 | 0.008035 | 0.00604  | 0.005936 | 0.005893 | 0.005415 |
| 1964 | 0.01128 | 0.007974 | 0.007323 | 0.007271 | 0.007217 | 0.006839 |
| 1965 | 0.0335  | 0.01552  | 0.01088  | 0.01006  | 0.009897 | 0.008859 |
| 1966 | 0.01687 | 0.01238  | 0.01117  | 0.01095  | 0.01091  | 0.01054  |
| 1967 | 0.03859 | 0.0212   | 0.0146   | 0.01368  | 0.01346  | 0.01245  |
| 1968 | 0.026   | 0.01702  | 0.01467  | 0.01423  | 0.01411  | 0.01374  |
| 1969 | 0.02025 | 0.01601  | 0.01517  | 0.01502  | 0.01492  | 0.01462  |
| 1970 | 0.02174 | 0.01773  | 0.01646  | 0.01616  | 0.01613  | 0.01575  |
| 1971 | 0.032   | 0.02044  | 0.01794  | 0.01764  | 0.01759  | 0.01706  |
| 1972 | 0.03337 | 0.02197  | 0.01944  | 0.01891  | 0.01885  | 0.01828  |
| 1973 | 0.03054 | 0.02224  | 0.02006  | 0.01989  | 0.01976  | 0.01919  |



|      |         |         |         |         |         |         |
|------|---------|---------|---------|---------|---------|---------|
| 1974 | 0.02873 | 0.02309 | 0.02057 | 0.02046 | 0.02038 | 0.01993 |
| 1975 | 0.04041 | 0.02618 | 0.02283 | 0.02174 | 0.0215  | 0.02071 |
| 1976 | 0.03741 | 0.02682 | 0.02396 | 0.0235  | 0.02338 | 0.02268 |
| 1977 | 0.03088 | 0.02641 | 0.02465 | 0.02426 | 0.02419 | 0.02357 |
| 1978 | 0.07833 | 0.04288 | 0.03051 | 0.0281  | 0.02757 | 0.02577 |
| 1979 | 0.04641 | 0.03705 | 0.03113 | 0.02958 | 0.02925 | 0.02784 |
| 1980 | 0.04819 | 0.0332  | 0.02922 | 0.02857 | 0.02863 | 0.02818 |
| 1981 | 0.03865 | 0.03206 | 0.02956 | 0.02911 | 0.02906 | 0.02866 |
| 1982 | 0.04808 | 0.03856 | 0.03316 | 0.03159 | 0.03122 | 0.02986 |
| 1983 | 0.04003 | 0.03204 | 0.03034 | 0.03007 | 0.02992 | 0.02957 |
| 1984 | 0.04794 | 0.03494 | 0.03118 | 0.03054 | 0.03032 | 0.02952 |
| 1985 | 0.04352 | 0.03325 | 0.03099 | 0.03042 | 0.03018 | 0.02967 |
| 1986 | 0.06588 | 0.04388 | 0.0334  | 0.03154 | 0.03115 | 0.03014 |
| 1987 | 0.05939 | 0.03996 | 0.03312 | 0.03182 | 0.03149 | 0.03092 |
| 1988 | 0.03997 | 0.03285 | 0.03158 | 0.03131 | 0.03121 | 0.03086 |
| 1989 | 0.05527 | 0.03711 | 0.03233 | 0.03145 | 0.03152 | 0.0308  |
| 1990 | 0.05526 | 0.03717 | 0.03243 | 0.03172 | 0.03155 | 0.0309  |

#### Sorted results

| Prob.              | Peak    | 96 hr    | 21 Day   | 60 Day   | 90 Day   | Yearly   |
|--------------------|---------|----------|----------|----------|----------|----------|
| 0.032258064516129  | 0.07833 | 0.04388  | 0.0334   | 0.03182  | 0.03155  | 0.03092  |
| 0.0645161290322581 | 0.06588 | 0.04288  | 0.03316  | 0.03172  | 0.03152  | 0.0309   |
| 0.0967741935483871 | 0.05939 | 0.03996  | 0.03312  | 0.03159  | 0.03149  | 0.03086  |
| 0.129032258064516  | 0.05527 | 0.03856  | 0.03243  | 0.03154  | 0.03122  | 0.0308   |
| 0.161290322580645  | 0.05526 | 0.03717  | 0.03233  | 0.03145  | 0.03121  | 0.03014  |
| 0.193548387096774  | 0.04819 | 0.03711  | 0.03158  | 0.03131  | 0.03115  | 0.02986  |
| 0.225806451612903  | 0.04808 | 0.03705  | 0.03118  | 0.03054  | 0.03032  | 0.02967  |
| 0.258064516129032  | 0.04794 | 0.03494  | 0.03113  | 0.03042  | 0.03018  | 0.02957  |
| 0.290322580645161  | 0.04641 | 0.03325  | 0.03099  | 0.03007  | 0.02992  | 0.02952  |
| 0.32258064516129   | 0.04352 | 0.0332   | 0.03051  | 0.02958  | 0.02925  | 0.02866  |
| 0.354838709677419  | 0.04041 | 0.03285  | 0.03034  | 0.02911  | 0.02906  | 0.02818  |
| 0.387096774193548  | 0.04003 | 0.03206  | 0.02956  | 0.02857  | 0.02863  | 0.02784  |
| 0.419354838709677  | 0.03997 | 0.03204  | 0.02922  | 0.0281   | 0.02757  | 0.02577  |
| 0.451612903225806  | 0.03865 | 0.02682  | 0.02465  | 0.02426  | 0.02419  | 0.02357  |
| 0.483870967741936  | 0.03859 | 0.02641  | 0.02396  | 0.0235   | 0.02338  | 0.02268  |
| 0.516129032258065  | 0.03741 | 0.02618  | 0.02283  | 0.02174  | 0.0215   | 0.02071  |
| 0.548387096774194  | 0.0335  | 0.02309  | 0.02057  | 0.02046  | 0.02038  | 0.01993  |
| 0.580645161290323  | 0.03337 | 0.02224  | 0.02006  | 0.01989  | 0.01976  | 0.01919  |
| 0.612903225806452  | 0.032   | 0.02197  | 0.01944  | 0.01891  | 0.01885  | 0.01828  |
| 0.645161290322581  | 0.03088 | 0.0212   | 0.01794  | 0.01764  | 0.01759  | 0.01706  |
| 0.67741935483871   | 0.03054 | 0.02044  | 0.01646  | 0.01616  | 0.01613  | 0.01575  |
| 0.709677419354839  | 0.02873 | 0.01773  | 0.01517  | 0.01502  | 0.01492  | 0.01462  |
| 0.741935483870968  | 0.026   | 0.01702  | 0.01467  | 0.01423  | 0.01411  | 0.01374  |
| 0.774193548387097  | 0.02174 | 0.01601  | 0.0146   | 0.01368  | 0.01346  | 0.01245  |
| 0.806451612903226  | 0.02025 | 0.01552  | 0.01117  | 0.01095  | 0.01091  | 0.01054  |
| 0.838709677419355  | 0.01744 | 0.01238  | 0.01088  | 0.01006  | 0.009897 | 0.008859 |
| 0.870967741935484  | 0.01687 | 0.008035 | 0.007323 | 0.007271 | 0.007217 | 0.006839 |
| 0.903225806451613  | 0.01527 | 0.007974 | 0.00604  | 0.005936 | 0.005893 | 0.005415 |
| 0.935483870967742  | 0.01295 | 0.006695 | 0.004408 | 0.004071 | 0.003997 | 0.003408 |
| 0.967741935483871  | 0.01128 | 0.004784 | 0.002825 | 0.002402 | 0.002322 | 0.001574 |

0.1      0.058978   0.03982   0.033051   0.031585   0.031463   0.030854  
Average of yearly averages:      0.0205768333333333

Inputs generated by pe5.pl - Novemeber 2006

Data used for this run:

Output File: MINursery

Metfile: w14840.dvf

PRZM scenario: MINurserySTD.txt

EXAMS environment file: pond298.csv

Chemical Name: emamectin benzoate

| Description        | Variable Name | Value   | Units                   | Comments |
|--------------------|---------------|---------|-------------------------|----------|
| Molecular weight   | mwt           | 964.23  | g/mol                   |          |
| Henry's Law Const. | henry         | 3.8e-10 | atm-m <sup>3</sup> /mol |          |
| Vapor Pressure     | vapr          |         | torr                    |          |
| Solubility sol     | 93            | mg/L    |                         |          |
| Kd                 | Kd            | mg/L    |                         |          |



Koc Koc 265687 mg/L  
 Photolysis half-life kdp 23 days Half-life  
 Aerobic Aquatic Metabolism kbacw 215 days Halfife  
 Anaerobic Aquatic Metabolism kbacs 1281 days Halfife  
 Aerobic Soil Metabolism asm 107.5 days Halfife  
 Hydrolysis: pH 5 0 days Half-life  
 Hydrolysis: pH 7 0 days Half-life  
 Hydrolysis: pH 9 0 days Half-life  
 Method: CAM 2 integer See PRZM manual  
 Incorporation Depth: DEPI 0 cm  
 Application Rate: TAPP 0.017 kg/ha  
 Application Efficiency: APPEFF 0.99 fraction  
 Spray Drift DRFT 0.01 fraction of application rate applied to pond  
 Application Date Date 2-1 dd/mm or dd/mm or dd-mm or dd-mm  
 Interval 1 interval 7 days Set to 0 or delete line for single app.  
 app. rate 1 apprate 0.017 kg/ha  
 Interval 2 interval 7 days Set to 0 or delete line for single app.  
 app. rate 2 apprate 0.017 kg/ha  
 Interval 3 interval 7 days Set to 0 or delete line for single app.  
 app. rate 3 apprate 0.017 kg/ha  
 Interval 4 interval 7 days Set to 0 or delete line for single app.  
 app. rate 4 apprate 0.017 kg/ha  
 Interval 5 interval 7 days Set to 0 or delete line for single app.  
 app. rate 5 apprate 0.017 kg/ha  
 Record 17: FILTRA  
 IPSCND 1  
 UPTKF  
 Record 18: PLVKRT  
 PLDKRT  
 FEXTRC 0.5  
 Flag for Index Res. Run IR EPA Pond  
 Flag for runoff calc. RUNOFF none none, monthly or total(average of entire run)

stored as NJNursery.out

Chemical: emamectin benzoate

PRZM environment: NJNurserySTD.txt

modified Tuesday, 26 August 2008 at 05:16:42

EXAMS environment: pond298.exv

modified Tuesday, 26 August 2008 at 05:14:08

Metfile: w93730.dvf modified Tuesday, 26 August 2008 at 05:16:14

Water segment concentrations (ppb)

| Year | Peak    | 96 hr    | 21 Day   | 60 Day   | 90 Day   | Yearly   |
|------|---------|----------|----------|----------|----------|----------|
| 1961 | 0.01771 | 0.005159 | 0.003315 | 0.003049 | 0.002993 | 0.002325 |
| 1962 | 0.0353  | 0.01199  | 0.007738 | 0.007191 | 0.007044 | 0.005975 |
| 1963 | 0.03896 | 0.01619  | 0.01108  | 0.01019  | 0.0101   | 0.009028 |
| 1964 | 0.03208 | 0.02001  | 0.01346  | 0.01282  | 0.01283  | 0.01199  |
| 1965 | 0.02732 | 0.01708  | 0.0146   | 0.01418  | 0.01406  | 0.01357  |
| 1966 | 0.0723  | 0.03076  | 0.0197   | 0.01817  | 0.01779  | 0.0163   |
| 1967 | 0.07609 | 0.03636  | 0.02344  | 0.02147  | 0.02103  | 0.01938  |
| 1968 | 0.06048 | 0.03506  | 0.02516  | 0.0236   | 0.02338  | 0.02216  |
| 1969 | 0.08248 | 0.04398  | 0.02895  | 0.02622  | 0.02565  | 0.02388  |
| 1970 | 0.04527 | 0.03005  | 0.02662  | 0.02564  | 0.02544  | 0.02482  |
| 1971 | 0.05878 | 0.03416  | 0.02871  | 0.02778  | 0.0274   | 0.0261   |
| 1972 | 0.04798 | 0.03231  | 0.02815  | 0.02767  | 0.02747  | 0.0271   |
| 1973 | 0.0594  | 0.03539  | 0.02896  | 0.02798  | 0.02791  | 0.02755  |
| 1974 | 0.04478 | 0.03374  | 0.02916  | 0.02841  | 0.02849  | 0.02787  |
| 1975 | 0.05804 | 0.03641  | 0.03123  | 0.03019  | 0.03002  | 0.0289   |
| 1976 | 0.05147 | 0.035    | 0.03122  | 0.03017  | 0.03008  | 0.0295   |
| 1977 | 0.04443 | 0.03368  | 0.03168  | 0.03117  | 0.03113  | 0.03049  |
| 1978 | 0.08564 | 0.04562  | 0.03576  | 0.03449  | 0.03411  | 0.03236  |
| 1979 | 0.08677 | 0.04785  | 0.03792  | 0.03575  | 0.0353   | 0.03455  |
| 1980 | 0.05177 | 0.03883  | 0.03569  | 0.03494  | 0.03487  | 0.03427  |
| 1981 | 0.06256 | 0.04135  | 0.03604  | 0.03515  | 0.03496  | 0.03398  |
| 1982 | 0.04152 | 0.03527  | 0.03426  | 0.0339   | 0.03373  | 0.03292  |
| 1983 | 0.05684 | 0.03883  | 0.03525  | 0.03422  | 0.03388  | 0.03279  |
| 1984 | 0.09459 | 0.05023  | 0.03754  | 0.03565  | 0.03511  | 0.03363  |
| 1985 | 0.04203 | 0.03537  | 0.03396  | 0.0338   | 0.0338   | 0.03304  |
| 1986 | 0.08296 | 0.04594  | 0.03606  | 0.03492  | 0.03464  | 0.03358  |
| 1987 | 0.08326 | 0.04687  | 0.03737  | 0.03588  | 0.03539  | 0.0344   |

|      |         |         |         |         |         |         |
|------|---------|---------|---------|---------|---------|---------|
| 1988 | 0.04783 | 0.03742 | 0.03536 | 0.03466 | 0.03448 | 0.03405 |
| 1989 | 0.07302 | 0.04379 | 0.03597 | 0.0353  | 0.03508 | 0.03427 |
| 1990 | 0.07612 | 0.04494 | 0.03681 | 0.03558 | 0.03531 | 0.03426 |

#### Sorted results

| Prob.              | Peak | 96 hr   | 21 Day   | 60 Day   | 90 Day   | Yearly   |
|--------------------|------|---------|----------|----------|----------|----------|
| 0.032258064516129  |      | 0.09459 | 0.05023  | 0.03792  | 0.03588  | 0.03539  |
| 0.0645161290322581 |      | 0.08677 | 0.04785  | 0.03754  | 0.03575  | 0.03531  |
| 0.0967741935483871 |      | 0.08564 | 0.04687  | 0.03737  | 0.03565  | 0.0353   |
| 0.129032258064516  |      | 0.08326 | 0.04594  | 0.03681  | 0.03558  | 0.03511  |
| 0.161290322580645  |      | 0.08296 | 0.04562  | 0.03606  | 0.0353   | 0.03508  |
| 0.193548387096774  |      | 0.08248 | 0.04494  | 0.03604  | 0.03515  | 0.03496  |
| 0.225806451612903  |      | 0.07612 | 0.04398  | 0.03597  | 0.03494  | 0.03487  |
| 0.258064516129032  |      | 0.07609 | 0.04379  | 0.03576  | 0.03492  | 0.03464  |
| 0.290322580645161  |      | 0.07302 | 0.04135  | 0.03569  | 0.03466  | 0.03448  |
| 0.32258064516129   |      | 0.0723  | 0.03883  | 0.03536  | 0.03449  | 0.03411  |
| 0.354838709677419  |      | 0.06256 | 0.03883  | 0.03525  | 0.03422  | 0.03388  |
| 0.387096774193548  |      | 0.06048 | 0.03742  | 0.03426  | 0.0339   | 0.0338   |
| 0.419354838709677  |      | 0.0594  | 0.03641  | 0.03396  | 0.0338   | 0.03373  |
| 0.451612903225806  |      | 0.05878 | 0.03636  | 0.03168  | 0.03117  | 0.03113  |
| 0.483870967741936  |      | 0.05804 | 0.03539  | 0.03123  | 0.03019  | 0.03008  |
| 0.516129032258065  |      | 0.05684 | 0.03537  | 0.03122  | 0.03017  | 0.03002  |
| 0.548387096774194  |      | 0.05177 | 0.03527  | 0.02916  | 0.02841  | 0.02849  |
| 0.580645161290323  |      | 0.05147 | 0.03506  | 0.02896  | 0.02798  | 0.02791  |
| 0.612903225806452  |      | 0.04798 | 0.035    | 0.02895  | 0.02778  | 0.02747  |
| 0.645161290322581  |      | 0.04783 | 0.03416  | 0.02871  | 0.02767  | 0.0274   |
| 0.67741935483871   |      | 0.04527 | 0.03374  | 0.02815  | 0.02622  | 0.02565  |
| 0.709677419354839  |      | 0.04478 | 0.03368  | 0.02662  | 0.02564  | 0.02544  |
| 0.741935483870968  |      | 0.04443 | 0.03231  | 0.02516  | 0.0236   | 0.02338  |
| 0.774193548387097  |      | 0.04203 | 0.03076  | 0.02344  | 0.02147  | 0.02103  |
| 0.806451612903226  |      | 0.04152 | 0.03005  | 0.0197   | 0.01817  | 0.01779  |
| 0.838709677419355  |      | 0.03896 | 0.02001  | 0.0146   | 0.01418  | 0.01406  |
| 0.870967741935484  |      | 0.0353  | 0.01708  | 0.01346  | 0.01282  | 0.01283  |
| 0.903225806451613  |      | 0.03208 | 0.01619  | 0.01108  | 0.01019  | 0.0101   |
| 0.935483870967742  |      | 0.02732 | 0.01199  | 0.007738 | 0.007191 | 0.007044 |
| 0.967741935483871  |      | 0.01771 | 0.005159 | 0.003315 | 0.003049 | 0.002993 |

|     |          |          |          |          |          |         |
|-----|----------|----------|----------|----------|----------|---------|
| 0.1 | 0.085402 | 0.046777 | 0.037314 | 0.035643 | 0.035281 | 0.03427 |
|-----|----------|----------|----------|----------|----------|---------|

Average of yearly averages: 0.0261679333333333

Inputs generated by pe5.pl - November 2006

Data used for this run:

Output File: NJNursery

Metfile: w93730.dvf

PRZM scenario: NJNurserySTD.txt

EXAMS environment file: pond298.exv

Chemical Name: emamectin benzoate

| Description                  | Variable Name | Value   | Units                                        | Comments        |
|------------------------------|---------------|---------|----------------------------------------------|-----------------|
| Molecular weight             | mwt           | 964.23  | g/mol                                        |                 |
| Henry's Law Const.           | henry         | 3.8e-10 | atm-m <sup>3</sup> /mol                      |                 |
| Vapor Pressure               | vapr          |         | torr                                         |                 |
| Solubility                   | sol           | 93      | mg/L                                         |                 |
| Kd                           | Kd            |         | mg/L                                         |                 |
| Koc                          | Koc           | 265687  | mg/L                                         |                 |
| Photolysis half-life         | kdp           | 23      | days                                         | Half-life       |
| Aerobic Aquatic Metabolism   | kbacw         | 215     | days                                         | Halfife         |
| Anaerobic Aquatic Metabolism | kbacs         | 1281    | days                                         | Halfife         |
| Aerobic Soil Metabolism      | asm           | 107.5   | days                                         | Halfife         |
| Hydrolysis:                  | pH 5          | 0       | days                                         | Half-life       |
| Hydrolysis:                  | pH 7          | 0       | days                                         | Half-life       |
| Hydrolysis:                  | pH 9          | 0       | days                                         | Half-life       |
| Method:                      | CAM           | 2       | integer                                      | See PRZM manual |
| Incorporation Depth:         | DEPI          | 0       | cm                                           |                 |
| Application Rate:            | TAPP          | 0.017   | kg/ha                                        |                 |
| Application Efficiency:      | APPEFF        | 0.99    | fraction                                     |                 |
| Spray Drift                  | DRFT          | 0.01    | fraction of application rate applied to pond |                 |
| Application Date             | Date          | 2-1     | dd/mm or dd/mmm or dd-mm or dd-mmm           |                 |

|                     |       |       |                                         |
|---------------------|-------|-------|-----------------------------------------|
| Interval 1 interval | 7     | days  | Set to 0 or delete line for single app. |
| app. rate 1 apprate | 0.017 | kg/ha |                                         |
| Interval 2 interval | 7     | days  | Set to 0 or delete line for single app. |
| app. rate 2 apprate | 0.017 | kg/ha |                                         |
| Interval 3 interval | 7     | days  | Set to 0 or delete line for single app. |
| app. rate 3 apprate | 0.017 | kg/ha |                                         |
| Interval 4 interval | 7     | days  | Set to 0 or delete line for single app. |
| app. rate 4 apprate | 0.017 | kg/ha |                                         |
| Interval 5 interval | 7     | days  | Set to 0 or delete line for single app. |
| app. rate 5 apprate | 0.017 | kg/ha |                                         |

Record 17: FILTRA

IPSCND 1

UPTKF

Record 18: PLVKRT

PLDKRT

FEXTRC 0.5

Flag for Index Res. Run

IR

EPA Pond

Flag for runoff calc. RUNOFF none

none, monthly or total(average of entire run)

stored as ORNursery.out

Chemical: emamectin benzoate

PRZM environment: ORNurserySTD.txt

modified Tuesday, 26 August 2008 at 05:16:42

EXAMS environment: pond298.exv

modified Tuesday, 26 August 2008 at 05:14:08

Metfile: w24229.dvf modified Tuesday, 26 August 2008 at 05:15:54

Water segment concentrations (ppb)

| Year | Peak     | 96 hr    | 21 Day   | 60 Day   | 90 Day   | Yearly   |
|------|----------|----------|----------|----------|----------|----------|
| 1961 | 0.0135   | 0.004517 | 0.002069 | 0.001423 | 0.001305 | 0.001155 |
| 1962 | 0.006648 | 0.002831 | 0.002192 | 0.001923 | 0.001854 | 0.001771 |
| 1963 | 0.00877  | 0.004799 | 0.003402 | 0.00283  | 0.002733 | 0.002582 |
| 1964 | 0.01216  | 0.006764 | 0.004464 | 0.003767 | 0.003591 | 0.003315 |
| 1965 | 0.01536  | 0.006598 | 0.004922 | 0.004347 | 0.004187 | 0.003962 |
| 1966 | 0.009404 | 0.005824 | 0.004948 | 0.004722 | 0.004634 | 0.004402 |
| 1967 | 0.009912 | 0.00621  | 0.005562 | 0.005171 | 0.005051 | 0.004759 |
| 1968 | 0.01334  | 0.008494 | 0.006239 | 0.005789 | 0.005644 | 0.005424 |
| 1969 | 0.0109   | 0.007554 | 0.006554 | 0.006299 | 0.006135 | 0.00584  |
| 1970 | 0.01692  | 0.01023  | 0.007802 | 0.007386 | 0.007193 | 0.006765 |
| 1971 | 0.0124   | 0.008251 | 0.007632 | 0.007362 | 0.007237 | 0.006956 |
| 1972 | 0.01493  | 0.009917 | 0.008309 | 0.007842 | 0.007705 | 0.007316 |
| 1973 | 0.01256  | 0.008698 | 0.008104 | 0.007858 | 0.007699 | 0.007341 |
| 1974 | 0.01745  | 0.01196  | 0.009202 | 0.008484 | 0.008298 | 0.007838 |
| 1975 | 0.01615  | 0.01108  | 0.009249 | 0.008734 | 0.008556 | 0.008117 |
| 1976 | 0.0144   | 0.009793 | 0.008807 | 0.008675 | 0.008541 | 0.008148 |
| 1977 | 0.01327  | 0.009407 | 0.008812 | 0.008548 | 0.008397 | 0.008026 |
| 1978 | 0.01327  | 0.009928 | 0.00894  | 0.008609 | 0.008451 | 0.00804  |
| 1979 | 0.01593  | 0.01005  | 0.008886 | 0.008557 | 0.008422 | 0.008039 |
| 1980 | 0.01548  | 0.01086  | 0.009374 | 0.008919 | 0.00873  | 0.008269 |
| 1981 | 0.01347  | 0.009613 | 0.00903  | 0.008858 | 0.008721 | 0.008324 |
| 1982 | 0.02096  | 0.01197  | 0.009586 | 0.009326 | 0.00917  | 0.008781 |
| 1983 | 0.01723  | 0.01125  | 0.009692 | 0.009475 | 0.009465 | 0.009118 |
| 1984 | 0.01425  | 0.01039  | 0.009845 | 0.009567 | 0.00941  | 0.009114 |
| 1985 | 0.01428  | 0.01042  | 0.009827 | 0.009557 | 0.00941  | 0.009029 |
| 1986 | 0.01421  | 0.01029  | 0.009717 | 0.009528 | 0.009376 | 0.008937 |
| 1987 | 0.03269  | 0.01579  | 0.01098  | 0.01014  | 0.009938 | 0.009445 |
| 1988 | 0.01476  | 0.01114  | 0.01021  | 0.009913 | 0.009758 | 0.009371 |
| 1989 | 0.0145   | 0.01058  | 0.009986 | 0.009786 | 0.009716 | 0.009314 |
| 1990 | 0.01504  | 0.01135  | 0.01028  | 0.009883 | 0.009712 | 0.009212 |

Sorted results

| Prob.              | Peak    | 96 hr   | 21 Day   | 60 Day   | 90 Day   | Yearly   |
|--------------------|---------|---------|----------|----------|----------|----------|
| 0.032258064516129  | 0.03269 | 0.01579 | 0.01098  | 0.01014  | 0.009938 | 0.009445 |
| 0.0645161290322581 | 0.02096 | 0.01197 | 0.01028  | 0.009913 | 0.009758 | 0.009371 |
| 0.0967741935483871 | 0.01745 | 0.01196 | 0.01021  | 0.009883 | 0.009716 | 0.009314 |
| 0.129032258064516  | 0.01723 | 0.01135 | 0.009986 | 0.009786 | 0.009712 | 0.009212 |
| 0.161290322580645  | 0.01692 | 0.01125 | 0.009845 | 0.009567 | 0.009465 | 0.009118 |
| 0.193548387096774  | 0.01615 | 0.01114 | 0.009827 | 0.009557 | 0.00941  | 0.009114 |
| 0.225806451612903  | 0.01593 | 0.01108 | 0.009717 | 0.009528 | 0.00941  | 0.009029 |
| 0.258064516129032  | 0.01548 | 0.01086 | 0.009692 | 0.009475 | 0.009376 | 0.008937 |



|                   |          |          |          |          |          |          |
|-------------------|----------|----------|----------|----------|----------|----------|
| 0.290322580645161 | 0.01536  | 0.01058  | 0.009586 | 0.009326 | 0.00917  | 0.008781 |
| 0.32258064516129  | 0.01504  | 0.01042  | 0.009374 | 0.008919 | 0.00873  | 0.008324 |
| 0.354838709677419 | 0.01493  | 0.01039  | 0.009249 | 0.008858 | 0.008721 | 0.008269 |
| 0.387096774193548 | 0.01476  | 0.01029  | 0.009202 | 0.008734 | 0.008556 | 0.008148 |
| 0.419354838709677 | 0.0145   | 0.01023  | 0.00903  | 0.008675 | 0.008541 | 0.008117 |
| 0.451612903225806 | 0.0144   | 0.01005  | 0.00894  | 0.008609 | 0.008451 | 0.00804  |
| 0.483870967741936 | 0.01428  | 0.009928 | 0.008886 | 0.008557 | 0.008422 | 0.008039 |
| 0.516129032258065 | 0.01425  | 0.009917 | 0.008812 | 0.008548 | 0.008397 | 0.008026 |
| 0.548387096774194 | 0.01421  | 0.009793 | 0.008807 | 0.008484 | 0.008298 | 0.007838 |
| 0.580645161290323 | 0.0135   | 0.009613 | 0.008309 | 0.007858 | 0.007705 | 0.007341 |
| 0.612903225806452 | 0.01347  | 0.009407 | 0.008104 | 0.007842 | 0.007699 | 0.007316 |
| 0.645161290322581 | 0.01334  | 0.008698 | 0.007802 | 0.007386 | 0.007237 | 0.006956 |
| 0.67741935483871  | 0.01327  | 0.008494 | 0.007632 | 0.007362 | 0.007193 | 0.006765 |
| 0.709677419354839 | 0.01327  | 0.008251 | 0.006554 | 0.006299 | 0.006135 | 0.00584  |
| 0.741935483870968 | 0.01256  | 0.007554 | 0.006239 | 0.005789 | 0.005644 | 0.005424 |
| 0.774193548387097 | 0.0124   | 0.006764 | 0.005562 | 0.005171 | 0.005051 | 0.004759 |
| 0.806451612903226 | 0.01216  | 0.006598 | 0.004948 | 0.004722 | 0.004634 | 0.004402 |
| 0.838709677419355 | 0.0109   | 0.00621  | 0.004922 | 0.004347 | 0.004187 | 0.003962 |
| 0.870967741935484 | 0.009912 | 0.005824 | 0.004464 | 0.003767 | 0.003591 | 0.003315 |
| 0.903225806451613 | 0.009404 | 0.004799 | 0.003402 | 0.00283  | 0.002733 | 0.002582 |
| 0.935483870967742 | 0.00877  | 0.004517 | 0.002192 | 0.001923 | 0.001854 | 0.001771 |
| 0.967741935483871 | 0.006648 | 0.002831 | 0.002069 | 0.001423 | 0.001305 | 0.001155 |

0.1      0.017428   0.011899   0.0101876   0.0098733   0.0097156   0.0093038  
Average of yearly averages:      0.006957

Inputs generated by pe5.pl - November 2006

Data used for this run:

Output File: ORNursery

Metfile: w24229.dvf

PRZM scenario: ORNurserySTD.bct

EXAMS environment file: pond298.exv

Chemical Name: emamectin benzoate

| Description                  | Variable Name | Value   | Units                                        | Comments        |
|------------------------------|---------------|---------|----------------------------------------------|-----------------|
| Molecular weight             | mwt           | 964.23  | g/mol                                        |                 |
| Henry's Law Const.           | henry         | 3.8e-10 | atm-m <sup>3</sup> /mol                      |                 |
| Vapor Pressure               | vap           |         | torr                                         |                 |
| Solubility                   | sol           | 93      | mg/L                                         |                 |
| Kd                           | Kd            |         | mg/L                                         |                 |
| Koc                          | Koc           | 265687  | mg/L                                         |                 |
| Photolysis half-life         | kdp           | 23      | days                                         | Half-life       |
| Aerobic Aquatic Metabolism   | kbacw         | 215     | days                                         | Half-life       |
| Anaerobic Aquatic Metabolism | kbacs         | 1281    | days                                         | Half-life       |
| Aerobic Soil Metabolism      | asm           | 107.5   | days                                         | Half-life       |
| Hydrolysis:                  | pH 5          | 0       | days                                         | Half-life       |
| Hydrolysis:                  | pH 7          | 0       | days                                         | Half-life       |
| Hydrolysis:                  | pH 9          | 0       | days                                         | Half-life       |
| Method:                      | CAM           | 2       | integer                                      | See PRZM manual |
| Incorporation Depth:         | DEP1          | 0       | cm                                           |                 |
| Application Rate:            | TAPP          | 0.017   | kg/ha                                        |                 |
| Application Efficiency:      | APPEFF        | 0.99    | fraction                                     |                 |
| Spray Drift                  | DRFT          | 0.01    | fraction of application rate applied to pond |                 |
| Application Date             | Date          | 2-1     | dd/mm or dd/mm or dd-mm or dd-mmm            |                 |
| Interval 1 interval          | 7             | days    | Set to 0 or delete line for single app.      |                 |
| app. rate 1 apprate          | 0.017         | kg/ha   |                                              |                 |
| Interval 2 interval          | 7             | days    | Set to 0 or delete line for single app.      |                 |
| app. rate 2 apprate          | 0.017         | kg/ha   |                                              |                 |
| Interval 3 interval          | 7             | days    | Set to 0 or delete line for single app.      |                 |
| app. rate 3 apprate          | 0.017         | kg/ha   |                                              |                 |
| Interval 4 interval          | 7             | days    | Set to 0 or delete line for single app.      |                 |
| app. rate 4 apprate          | 0.017         | kg/ha   |                                              |                 |
| Interval 5 interval          | 7             | days    | Set to 0 or delete line for single app.      |                 |
| app. rate 5 apprate          | 0.017         | kg/ha   |                                              |                 |

Record 17: FILTRA

IPSCND 1

UPTKF

Record 18: PLVKRT

PLDKRT  
FEXTRC 0.5  
Flag for Index Res. Run IR EPA Pond  
Flag for runoff calc. RUNOFF none none, monthly or total(average of entire run)

stored as TNNursery.out

Chemical: emamectin benzoate

PRZM environment: TNNurserySTD.txt modified Tuesday, 26 August 2008 at 05:16:42

EXAMS environment: pond298.exv modified Tuesday, 26 August 2008 at 05:14:08

Metfile: w13882.dvf modified Tuesday, 26 August 2008 at 05:14:38

Water segment concentrations (ppb)

| Year | Peak    | 96 hr   | 21 Day   | 60 Day   | 90 Day   | Yearly   |
|------|---------|---------|----------|----------|----------|----------|
| 1961 | 0.04028 | 0.01291 | 0.00684  | 0.005118 | 0.005015 | 0.003144 |
| 1962 | 0.04141 | 0.01596 | 0.009758 | 0.008911 | 0.008863 | 0.007307 |
| 1963 | 0.0375  | 0.01822 | 0.01561  | 0.01365  | 0.01325  | 0.0112   |
| 1964 | 0.07823 | 0.03026 | 0.01892  | 0.01787  | 0.01758  | 0.01571  |
| 1965 | 0.08322 | 0.03475 | 0.02199  | 0.02017  | 0.01987  | 0.01855  |
| 1966 | 0.0556  | 0.02882 | 0.02248  | 0.02134  | 0.02101  | 0.01985  |
| 1967 | 0.09332 | 0.04836 | 0.02921  | 0.02583  | 0.0251   | 0.02263  |
| 1968 | 0.05498 | 0.0329  | 0.02622  | 0.02518  | 0.0249   | 0.02384  |
| 1969 | 0.07491 | 0.03734 | 0.02823  | 0.0263   | 0.02584  | 0.0245   |
| 1970 | 0.06192 | 0.03552 | 0.02892  | 0.02758  | 0.02758  | 0.02614  |
| 1971 | 0.07133 | 0.04018 | 0.03096  | 0.02934  | 0.02888  | 0.02741  |
| 1972 | 0.1188  | 0.05188 | 0.03672  | 0.0343   | 0.03381  | 0.03105  |
| 1973 | 0.09144 | 0.04869 | 0.04031  | 0.03732  | 0.03715  | 0.03476  |
| 1974 | 0.08851 | 0.04942 | 0.04039  | 0.03794  | 0.03751  | 0.03605  |
| 1975 | 0.06743 | 0.04396 | 0.04006  | 0.03875  | 0.03832  | 0.03677  |
| 1976 | 0.1008  | 0.05514 | 0.04405  | 0.04232  | 0.04161  | 0.03912  |
| 1977 | 0.1364  | 0.06436 | 0.0462   | 0.04291  | 0.04216  | 0.04012  |
| 1978 | 0.05076 | 0.04417 | 0.04169  | 0.04108  | 0.04083  | 0.0398   |
| 1979 | 0.1295  | 0.06764 | 0.04899  | 0.04624  | 0.04567  | 0.042    |
| 1980 | 0.0843  | 0.05441 | 0.04597  | 0.04496  | 0.04454  | 0.04295  |
| 1981 | 0.06833 | 0.0484  | 0.04381  | 0.04308  | 0.04302  | 0.0418   |
| 1982 | 0.0701  | 0.04817 | 0.04309  | 0.04185  | 0.04166  | 0.04097  |
| 1983 | 0.09571 | 0.0608  | 0.04566  | 0.04304  | 0.04251  | 0.04064  |
| 1984 | 0.08153 | 0.05619 | 0.04571  | 0.04304  | 0.0431   | 0.04095  |
| 1985 | 0.0576  | 0.04382 | 0.04108  | 0.04064  | 0.0404   | 0.03975  |
| 1986 | 0.07944 | 0.04916 | 0.04103  | 0.03998  | 0.03978  | 0.039    |
| 1987 | 0.08282 | 0.05055 | 0.04381  | 0.04196  | 0.04145  | 0.03943  |
| 1988 | 0.06535 | 0.04575 | 0.04195  | 0.04084  | 0.04035  | 0.03924  |
| 1989 | 0.1044  | 0.0603  | 0.0497   | 0.04581  | 0.04491  | 0.04151  |
| 1990 | 0.06727 | 0.05124 | 0.04533  | 0.04434  | 0.04421  | 0.04261  |

#### Sorted results

| Prob.              | Peak    | 96 hr   | 21 Day  | 60 Day  | 90 Day  | Yearly  |
|--------------------|---------|---------|---------|---------|---------|---------|
| 0.032258064516129  | 0.1364  | 0.06764 | 0.0497  | 0.04624 | 0.04567 | 0.04295 |
| 0.0645161290322581 | 0.1295  | 0.06436 | 0.04899 | 0.04581 | 0.04491 | 0.04261 |
| 0.0967741935483871 | 0.1188  | 0.0608  | 0.0462  | 0.04496 | 0.04454 | 0.042   |
| 0.129032258064516  | 0.1044  | 0.0603  | 0.04597 | 0.04434 | 0.04421 | 0.0418  |
| 0.161290322580645  | 0.1008  | 0.05619 | 0.04571 | 0.04308 | 0.0431  | 0.04151 |
| 0.193548387096774  | 0.09571 | 0.05514 | 0.04566 | 0.04304 | 0.04302 | 0.04097 |
| 0.225806451612903  | 0.09332 | 0.05441 | 0.04533 | 0.04304 | 0.04251 | 0.04095 |
| 0.258064516129032  | 0.09144 | 0.05188 | 0.04405 | 0.04291 | 0.04216 | 0.04064 |
| 0.290322580645161  | 0.08851 | 0.05124 | 0.04381 | 0.04232 | 0.04166 | 0.04012 |
| 0.32258064516129   | 0.0843  | 0.05055 | 0.04381 | 0.04196 | 0.04161 | 0.0398  |
| 0.354838709677419  | 0.08322 | 0.04942 | 0.04309 | 0.04185 | 0.04145 | 0.03975 |
| 0.387096774193548  | 0.08282 | 0.04916 | 0.04195 | 0.04108 | 0.04083 | 0.03943 |
| 0.419354838709677  | 0.08153 | 0.04869 | 0.04169 | 0.04084 | 0.0404  | 0.03924 |
| 0.451612903225806  | 0.07944 | 0.0484  | 0.04108 | 0.04064 | 0.04035 | 0.03912 |
| 0.483870967741936  | 0.07823 | 0.04836 | 0.04103 | 0.03998 | 0.03978 | 0.039   |
| 0.516129032258065  | 0.07491 | 0.04817 | 0.04039 | 0.03875 | 0.03832 | 0.03677 |
| 0.548387096774194  | 0.07133 | 0.04575 | 0.04031 | 0.03794 | 0.03751 | 0.03605 |
| 0.580645161290323  | 0.0701  | 0.04417 | 0.04006 | 0.03732 | 0.03715 | 0.03476 |
| 0.612903225806452  | 0.06833 | 0.04396 | 0.03672 | 0.0343  | 0.03381 | 0.03105 |
| 0.645161290322581  | 0.06743 | 0.04382 | 0.03096 | 0.02934 | 0.02888 | 0.02741 |
| 0.67741935483871   | 0.06727 | 0.04018 | 0.02921 | 0.02758 | 0.02758 | 0.02614 |
| 0.709677419354839  | 0.06535 | 0.03734 | 0.02892 | 0.0263  | 0.02584 | 0.0245  |



|                             |         |         |          |          |          |           |
|-----------------------------|---------|---------|----------|----------|----------|-----------|
| 0.741935483870968           | 0.06192 | 0.03552 | 0.02823  | 0.02583  | 0.0251   | 0.02384   |
| 0.774193548387097           | 0.0576  | 0.03475 | 0.02622  | 0.02518  | 0.0249   | 0.02263   |
| 0.806451612903226           | 0.0556  | 0.0329  | 0.02248  | 0.02134  | 0.02101  | 0.01985   |
| 0.838709677419355           | 0.05498 | 0.03026 | 0.02199  | 0.02017  | 0.01987  | 0.01855   |
| 0.870967741935484           | 0.05076 | 0.02882 | 0.01892  | 0.01787  | 0.01758  | 0.01571   |
| 0.903225806451613           | 0.04141 | 0.01822 | 0.01561  | 0.01365  | 0.01325  | 0.0112    |
| 0.935483870967742           | 0.04028 | 0.01596 | 0.009758 | 0.008911 | 0.008863 | 0.007307  |
| 0.967741935483871           | 0.0375  | 0.01291 | 0.00684  | 0.005118 | 0.005015 | 0.003144  |
| 0.1                         | 0.11736 | 0.06075 | 0.046177 | 0.044898 | 0.044507 | 0.04198   |
| Average of yearly averages: |         |         |          |          |          | 0.0316267 |

Inputs generated by pe5.pl - November 2006

Data used for this run:

Output File: TNNursery

Metfile: w13882.dvf

PRZM scenario: TNNurserySTD.txt

EXAMS environment file: pond298.exv

Chemical Name: emamectin benzoate

| Description                  | Variable Name | Value   | Units                                        | Comments        |
|------------------------------|---------------|---------|----------------------------------------------|-----------------|
| Molecular weight             | mwt           | 964.23  | g/mol                                        |                 |
| Henry's Law Const.           | henry         | 3.8e-10 | atm-m <sup>3</sup> /mol                      |                 |
| Vapor Pressure               | vapr          |         | torr                                         |                 |
| Solubility sol               | 93            | mg/L    |                                              |                 |
| Kd                           | Kd            |         | mg/L                                         |                 |
| Koc                          | Koc           | 265687  | mg/L                                         |                 |
| Photolysis half-life         | kdp           | 23      | days                                         | Half-life       |
| Aerobic Aquatic Metabolism   | kbacw         | 215     | days                                         | Halfife         |
| Anaerobic Aquatic Metabolism | kbacs         | 1281    | days                                         | Halfife         |
| Aerobic Soil Metabolism      | asm           | 107.5   | days                                         | Halfife         |
| Hydrolysis:                  | pH 5          | 0       | days                                         | Half-life       |
| Hydrolysis:                  | pH 7          | 0       | days                                         | Half-life       |
| Hydrolysis:                  | pH 9          | 0       | days                                         | Half-life       |
| Method:                      | CAM           | 2       | integer                                      | See PRZM manual |
| Incorporation Depth:         | DEPI          | 0       | cm                                           |                 |
| Application Rate:            | TAPP          | 0.017   | kg/ha                                        |                 |
| Application Efficiency:      | APPEFF        | 0.99    | fraction                                     |                 |
| Spray Drift                  | DRFT          | 0.01    | fraction of application rate applied to pond |                 |
| Application Date             | Date          | 15-4    | dd/mm or dd/mmim or dd-mm or dd-mmm          |                 |
| Interval 1 interval          | 7             | days    | Set to 0 or delete line for single app.      |                 |
| app. rate 1 apprate          | 0.017         | kg/ha   |                                              |                 |
| Interval 2 interval          | 7             | days    | Set to 0 or delete line for single app.      |                 |
| app. rate 2 apprate          | 0.017         | kg/ha   |                                              |                 |
| Interval 3 interval          | 7             | days    | Set to 0 or delete line for single app.      |                 |
| app. rate 3 apprate          | 0.017         | kg/ha   |                                              |                 |
| Interval 4 interval          | 7             | days    | Set to 0 or delete line for single app.      |                 |
| app. rate 4 apprate          | 0.017         | kg/ha   |                                              |                 |
| Interval 5 interval          | 7             | days    | Set to 0 or delete line for single app.      |                 |
| app. rate 5 apprate          | 0.017         | kg/ha   |                                              |                 |

Record 17: FILTRA

IPSCND 1

UPTKF

Record 18: PLVKRT

PLDKRT

FEXTRC 0.5

Flag for Index Res. Run

IR

EPA Pond

Flag for runoff calc. RUNOFF

none

none, monthly or total(average of entire run)

### Group 9 Cucurbits:

stored as FLCuc.out

Chemical: emamectin benzoate

PRZM environment: FLCucumberSTD.txt modified Tuesday, 26 August 2008 at 05:16:38

EXAMS environment: pond298.exv modified Tuesday, 26 August 2008 at 05:14:08

Metfile: w12844.dvf modified Tuesday, 26 August 2008 at 05:14:22

Water segment concentrations (ppb)



| Year | Peak     | 96 hr    | 21 Day   | 60 Day    | 90 Day    | Yearly    |
|------|----------|----------|----------|-----------|-----------|-----------|
| 1961 | 0.005686 | 0.001828 | 0.001218 | 0.0007691 | 0.0005931 | 0.0003208 |
| 1962 | 0.01237  | 0.004631 | 0.002912 | 0.002411  | 0.002234  | 0.001665  |
| 1963 | 0.03148  | 0.01072  | 0.005006 | 0.003989  | 0.003782  | 0.003048  |
| 1964 | 0.02299  | 0.01018  | 0.006938 | 0.006516  | 0.006406  | 0.00571   |
| 1965 | 0.01587  | 0.009455 | 0.007873 | 0.007392  | 0.007281  | 0.006755  |
| 1966 | 0.03146  | 0.01778  | 0.01064  | 0.0102    | 0.01      | 0.009295  |
| 1967 | 0.02025  | 0.01232  | 0.01066  | 0.01018   | 0.01006   | 0.00986   |
| 1968 | 0.03453  | 0.01883  | 0.01431  | 0.01281   | 0.0124    | 0.01107   |
| 1969 | 0.03072  | 0.01713  | 0.01386  | 0.01315   | 0.01298   | 0.01244   |
| 1970 | 0.03935  | 0.02039  | 0.01638  | 0.01482   | 0.0147    | 0.01394   |
| 1971 | 0.03304  | 0.01845  | 0.01419  | 0.01381   | 0.01356   | 0.01311   |
| 1972 | 0.03913  | 0.01983  | 0.01598  | 0.01544   | 0.01518   | 0.01391   |
| 1973 | 0.02244  | 0.01559  | 0.01412  | 0.01391   | 0.01377   | 0.01345   |
| 1974 | 0.05066  | 0.0256   | 0.01661  | 0.01486   | 0.01463   | 0.01365   |
| 1975 | 0.0233   | 0.01621  | 0.01335  | 0.01295   | 0.01271   | 0.01246   |
| 1976 | 0.03938  | 0.02227  | 0.01495  | 0.01378   | 0.01348   | 0.01276   |
| 1977 | 0.05198  | 0.02286  | 0.01593  | 0.01527   | 0.01479   | 0.01374   |
| 1978 | 0.03341  | 0.01893  | 0.01514  | 0.01458   | 0.01435   | 0.01406   |
| 1979 | 0.05359  | 0.02394  | 0.01633  | 0.01537   | 0.01502   | 0.0142    |
| 1980 | 0.0404   | 0.02083  | 0.01634  | 0.01542   | 0.01514   | 0.01468   |
| 1981 | 0.027    | 0.01728  | 0.01466  | 0.01423   | 0.01417   | 0.01389   |
| 1982 | 0.05354  | 0.02725  | 0.01748  | 0.01671   | 0.01672   | 0.01542   |
| 1983 | 0.05983  | 0.02836  | 0.01895  | 0.01791   | 0.01754   | 0.01676   |
| 1984 | 0.03799  | 0.02328  | 0.01865  | 0.01784   | 0.01763   | 0.01693   |
| 1985 | 0.0316   | 0.01998  | 0.01683  | 0.01653   | 0.01646   | 0.01595   |
| 1986 | 0.03967  | 0.02629  | 0.0182   | 0.01675   | 0.01659   | 0.01579   |
| 1987 | 0.03057  | 0.01925  | 0.01669  | 0.01621   | 0.01612   | 0.01555   |
| 1988 | 0.03615  | 0.02151  | 0.01777  | 0.01675   | 0.01649   | 0.01554   |
| 1989 | 0.03292  | 0.0199   | 0.01581  | 0.01502   | 0.01493   | 0.01436   |
| 1990 | 0.03183  | 0.01842  | 0.01455  | 0.01414   | 0.01392   | 0.01341   |

#### Sorted results

| Prob.              | Peak     | 96 hr    | 21 Day   | 60 Day    | 90 Day    | Yearly    |
|--------------------|----------|----------|----------|-----------|-----------|-----------|
| 0.032258064516129  | 0.05983  | 0.02836  | 0.01895  | 0.01791   | 0.01763   | 0.01693   |
| 0.0645161290322581 | 0.05359  | 0.02725  | 0.01865  | 0.01784   | 0.01754   | 0.01676   |
| 0.0967741935483871 | 0.05354  | 0.02629  | 0.0182   | 0.01675   | 0.01672   | 0.01595   |
| 0.129032258064516  | 0.05198  | 0.0256   | 0.01777  | 0.01675   | 0.01659   | 0.01579   |
| 0.161290322580645  | 0.05066  | 0.02394  | 0.01748  | 0.01671   | 0.01649   | 0.01555   |
| 0.193548387096774  | 0.0404   | 0.02328  | 0.01683  | 0.01653   | 0.01646   | 0.01554   |
| 0.225806451612903  | 0.03967  | 0.02286  | 0.01669  | 0.01621   | 0.01612   | 0.01542   |
| 0.258064516129032  | 0.03938  | 0.02227  | 0.01661  | 0.01544   | 0.01518   | 0.01468   |
| 0.290322580645161  | 0.03935  | 0.02151  | 0.01638  | 0.01542   | 0.01514   | 0.01436   |
| 0.32258064516129   | 0.03913  | 0.02083  | 0.01634  | 0.01537   | 0.01502   | 0.0142    |
| 0.354838709677419  | 0.03799  | 0.02039  | 0.01633  | 0.01527   | 0.01493   | 0.01406   |
| 0.387096774193548  | 0.03615  | 0.01998  | 0.01598  | 0.01502   | 0.01479   | 0.01394   |
| 0.419354838709677  | 0.03453  | 0.0199   | 0.01593  | 0.01486   | 0.0147    | 0.01391   |
| 0.451612903225806  | 0.03341  | 0.01983  | 0.01581  | 0.01482   | 0.01463   | 0.01389   |
| 0.483870967741936  | 0.03304  | 0.01925  | 0.01514  | 0.01458   | 0.01435   | 0.01374   |
| 0.516129032258065  | 0.03292  | 0.01893  | 0.01495  | 0.01423   | 0.01417   | 0.01365   |
| 0.548387096774194  | 0.03183  | 0.01883  | 0.01466  | 0.01414   | 0.01392   | 0.01345   |
| 0.580645161290323  | 0.0316   | 0.01845  | 0.01455  | 0.01391   | 0.01377   | 0.01341   |
| 0.612903225806452  | 0.03148  | 0.01842  | 0.01431  | 0.01381   | 0.01356   | 0.01311   |
| 0.645161290322581  | 0.03146  | 0.01778  | 0.01419  | 0.01378   | 0.01348   | 0.01276   |
| 0.67741935483871   | 0.03072  | 0.01728  | 0.01412  | 0.01315   | 0.01298   | 0.01246   |
| 0.709677419354839  | 0.03057  | 0.01713  | 0.01386  | 0.01295   | 0.01271   | 0.01244   |
| 0.741935483870968  | 0.027    | 0.01621  | 0.01335  | 0.01281   | 0.0124    | 0.01107   |
| 0.774193548387097  | 0.0233   | 0.01559  | 0.01066  | 0.0102    | 0.01006   | 0.00986   |
| 0.806451612903226  | 0.02299  | 0.01232  | 0.01064  | 0.01018   | 0.01      | 0.009295  |
| 0.838709677419355  | 0.02244  | 0.01072  | 0.007873 | 0.007392  | 0.007281  | 0.006755  |
| 0.870967741935484  | 0.02025  | 0.01018  | 0.006938 | 0.006516  | 0.006406  | 0.00571   |
| 0.903225806451613  | 0.01587  | 0.009455 | 0.005006 | 0.003989  | 0.003782  | 0.003048  |
| 0.935483870967742  | 0.01237  | 0.004631 | 0.002912 | 0.002411  | 0.002234  | 0.001665  |
| 0.967741935483871  | 0.005686 | 0.001828 | 0.001218 | 0.0007691 | 0.0005931 | 0.0003208 |

0.1 0.053384 0.026221 0.018157 0.01675 0.016707 0.015934

Average of yearly averages: 0.0121241266666667

Inputs generated by pe5.pl - November 2006

Data used for this run:

Output File: FLCuc

Metfile: w12844.dvf

PRZM scenario: FLCucumberSTD.txt

EXAMS environment file: pond298.exv

Chemical Name: emamectin benzoate

| Description | Variable Name | Value | Units | Comments |
|-------------|---------------|-------|-------|----------|
|-------------|---------------|-------|-------|----------|

|                  |     |        |       |  |
|------------------|-----|--------|-------|--|
| Molecular weight | mwt | 964.23 | g/mol |  |
|------------------|-----|--------|-------|--|

|                    |       |         |                         |  |
|--------------------|-------|---------|-------------------------|--|
| Henry's Law Const. | henry | 3.8e-10 | atm-m <sup>3</sup> /mol |  |
|--------------------|-------|---------|-------------------------|--|

|                |      |  |      |  |
|----------------|------|--|------|--|
| Vapor Pressure | vapr |  | torr |  |
|----------------|------|--|------|--|

|            |     |    |      |  |
|------------|-----|----|------|--|
| Solubility | sol | 93 | mg/L |  |
|------------|-----|----|------|--|

|    |    |  |      |  |
|----|----|--|------|--|
| Kd | Kd |  | mg/L |  |
|----|----|--|------|--|

|     |     |        |      |  |
|-----|-----|--------|------|--|
| Koc | Koc | 265687 | mg/L |  |
|-----|-----|--------|------|--|

|                      |     |    |      |           |
|----------------------|-----|----|------|-----------|
| Photolysis half-life | kdp | 23 | days | Half-life |
|----------------------|-----|----|------|-----------|

|                            |       |     |      |         |
|----------------------------|-------|-----|------|---------|
| Aerobic Aquatic Metabolism | kbacw | 215 | days | Halfife |
|----------------------------|-------|-----|------|---------|

|                              |       |      |      |         |
|------------------------------|-------|------|------|---------|
| Anaerobic Aquatic Metabolism | kbacs | 1281 | days | Halfife |
|------------------------------|-------|------|------|---------|

|                         |     |       |      |         |
|-------------------------|-----|-------|------|---------|
| Aerobic Soil Metabolism | asm | 107.5 | days | Halfife |
|-------------------------|-----|-------|------|---------|

|             |      |   |      |           |
|-------------|------|---|------|-----------|
| Hydrolysis: | pH 5 | 0 | days | Half-life |
|-------------|------|---|------|-----------|

|             |      |   |      |           |
|-------------|------|---|------|-----------|
| Hydrolysis: | pH 7 | 0 | days | Half-life |
|-------------|------|---|------|-----------|

|             |      |   |      |           |
|-------------|------|---|------|-----------|
| Hydrolysis: | pH 9 | 0 | days | Half-life |
|-------------|------|---|------|-----------|

|         |     |   |         |                 |
|---------|-----|---|---------|-----------------|
| Method: | CAM | 2 | integer | See PRZM manual |
|---------|-----|---|---------|-----------------|

|                      |      |   |    |  |
|----------------------|------|---|----|--|
| Incorporation Depth: | DEPI | 0 | cm |  |
|----------------------|------|---|----|--|

|                   |      |       |       |  |
|-------------------|------|-------|-------|--|
| Application Rate: | TAPP | 0.017 | kg/ha |  |
|-------------------|------|-------|-------|--|

|                         |        |      |          |  |
|-------------------------|--------|------|----------|--|
| Application Efficiency: | APPEFF | 0.99 | fraction |  |
|-------------------------|--------|------|----------|--|

|             |      |      |                                              |  |
|-------------|------|------|----------------------------------------------|--|
| Spray Drift | DRFT | 0.01 | fraction of application rate applied to pond |  |
|-------------|------|------|----------------------------------------------|--|

|                  |      |     |                                   |  |
|------------------|------|-----|-----------------------------------|--|
| Application Date | Date | 5-1 | dd/mm or dd/mm or dd-mm or dd-mmm |  |
|------------------|------|-----|-----------------------------------|--|

|                     |     |      |                                         |  |
|---------------------|-----|------|-----------------------------------------|--|
| Interval 1 interval | 327 | days | Set to 0 or delete line for single app. |  |
|---------------------|-----|------|-----------------------------------------|--|

|                     |       |       |  |  |
|---------------------|-------|-------|--|--|
| app. rate 1 apprate | 0.017 | kg/ha |  |  |
|---------------------|-------|-------|--|--|

|                     |   |      |                                         |  |
|---------------------|---|------|-----------------------------------------|--|
| Interval 2 interval | 7 | days | Set to 0 or delete line for single app. |  |
|---------------------|---|------|-----------------------------------------|--|

|                     |       |       |  |  |
|---------------------|-------|-------|--|--|
| app. rate 2 apprate | 0.017 | kg/ha |  |  |
|---------------------|-------|-------|--|--|

|                     |   |      |                                         |  |
|---------------------|---|------|-----------------------------------------|--|
| Interval 3 interval | 7 | days | Set to 0 or delete line for single app. |  |
|---------------------|---|------|-----------------------------------------|--|

|                     |       |       |  |  |
|---------------------|-------|-------|--|--|
| app. rate 3 apprate | 0.017 | kg/ha |  |  |
|---------------------|-------|-------|--|--|

|                     |   |      |                                         |  |
|---------------------|---|------|-----------------------------------------|--|
| Interval 4 interval | 7 | days | Set to 0 or delete line for single app. |  |
|---------------------|---|------|-----------------------------------------|--|

|                     |       |       |  |  |
|---------------------|-------|-------|--|--|
| app. rate 4 apprate | 0.017 | kg/ha |  |  |
|---------------------|-------|-------|--|--|

|                     |   |      |                                         |  |
|---------------------|---|------|-----------------------------------------|--|
| Interval 5 interval | 7 | days | Set to 0 or delete line for single app. |  |
|---------------------|---|------|-----------------------------------------|--|

|                     |       |       |  |  |
|---------------------|-------|-------|--|--|
| app. rate 5 apprate | 0.017 | kg/ha |  |  |
|---------------------|-------|-------|--|--|

Record 17: FILTRA

IPSCND 1

UPTKF

Record 18: PLVKRT

PLDKRT

FEXTRC 0.5

|                         |    |          |
|-------------------------|----|----------|
| Flag for Index Res. Run | IR | EPA Pond |
|-------------------------|----|----------|

|                       |             |                                               |
|-----------------------|-------------|-----------------------------------------------|
| Flag for runoff calc. | RUNOFF none | none, monthly or total(average of entire run) |
|-----------------------|-------------|-----------------------------------------------|

## APPENDIX 5.

### Risk Quotient Tables for Aquatic and Terrestrial Animals and Plants

#### *Freshwater Fish and Invertebrates, acute risk*

| Table 5-1. Acute RQs for Emamectin benzoate for Freshwater Fish and Invertebrates from use on Ornamentals and Cucurbits |                    |                                    |                                            |
|-------------------------------------------------------------------------------------------------------------------------|--------------------|------------------------------------|--------------------------------------------|
| Scenario                                                                                                                | Peak EEC<br>(µg/L) | Fish RQ <sup>1</sup><br>(EEC/LC50) | Invertebrate RQ <sup>2</sup><br>(EEC/EC50) |
| <i>Outdoor Ornamentals</i>                                                                                              |                    |                                    |                                            |
| CAnurserySTD                                                                                                            | 0.211              | <0.01                              | 0.21                                       |
| FLnurserySTD                                                                                                            | 0.071              | <0.01                              | 0.07                                       |
| MinurserySTD                                                                                                            | 0.059              | <0.01                              | 0.06                                       |
| NJnurserySTD                                                                                                            | 0.085              | <0.01                              | 0.09                                       |
| ORnurserySTD                                                                                                            | 0.017              | <0.01                              | 0.02                                       |
| TNnurserySTD                                                                                                            | 0.117              | <0.01                              | 0.12                                       |
| <i>Cucurbit</i>                                                                                                         |                    |                                    |                                            |
| FLcucumberSTD                                                                                                           | 0.053              | <0.01                              | 0.05                                       |

<sup>1</sup> based on the rainbow trout EC<sub>50</sub> of 174ppb

<sup>2</sup> based on the water flea EC<sub>50</sub> of 1 ppb

\*Values in red exceed the LOC for Acute listed species (RQ ≥ 0.05)

\*\*Values in red and italics exceed the LOC for acute listed species (RQ ≥ 0.05) and acute restricted use (RQ ≥ 0.1)

#### *Freshwater Fish and Invertebrates, chronic risk*

| Table 5-2. Chronic RQs for Emamectin benzoate for Freshwater Fish and Invertebrates from use on Ornamentals and Cucurbits |                             |                             |                                    |                                         |
|---------------------------------------------------------------------------------------------------------------------------|-----------------------------|-----------------------------|------------------------------------|-----------------------------------------|
| Scenario                                                                                                                  | 60-day Avg<br>EEC<br>(µg/L) | 21-day<br>Avg EEC<br>(µg/L) | Fish RQ <sup>1</sup><br>(EEC/NOEC) | Invertebrate RQ <sup>2</sup> (EEC/NOEC) |
| <i>Outdoor Ornamentals</i>                                                                                                |                             |                             |                                    |                                         |
| CAnurserySTD                                                                                                              | 0.052                       | 0.059                       | 0.01                               | 0.68                                    |
| FLnurserySTD                                                                                                              | 0.021                       | 0.023                       | <0.01                              | 0.26                                    |
| MinurserySTD                                                                                                              | 0.032                       | 0.033                       | <0.01                              | 0.38                                    |
| NJnurserySTD                                                                                                              | 0.036                       | 0.037                       | 0.01                               | 0.42                                    |
| ORnurserySTD                                                                                                              | 0.010                       | 0.010                       | <0.01                              | 0.12                                    |
| TNnurserySTD                                                                                                              | 0.045                       | 0.046                       | 0.01                               | 0.52                                    |
| <i>Cucurbit</i>                                                                                                           |                             |                             |                                    |                                         |
| FLcucumberSTD                                                                                                             | 0.017                       | 0.018                       | <0.01                              | 0.21                                    |

<sup>1</sup> based on the fathead minnow early life-stage NOAEC of 6.5 ppb

<sup>2</sup> based on the water flea life stage NOAEC of 0.088 ppb



## Marine/Estuarine Fish and Invertebrates Acute and Chronic Risk

**Table 5-3. Acute and Chronic RQs for Emamectin benzoate for Estuarine/Marine Organisms from use on Ornamentals and Cucurbits**

| EEC Modeled                | Peak EEC (µg/L) | 60-day Avg EEC ppb | 21-day Avg EEC ppb | Acute Fish RQ <sup>1</sup> (EEC/LC <sub>50</sub> ) | Acute Invertebrate RQ <sup>2</sup> (EEC/LC <sub>50</sub> ) | Chronic Fish RQ <sup>4</sup> (EEC/NOEC) | Chronic Invertebrate RQ <sup>3</sup> (EEC/NOEC) |
|----------------------------|-----------------|--------------------|--------------------|----------------------------------------------------|------------------------------------------------------------|-----------------------------------------|-------------------------------------------------|
| <i>Outdoor Ornamentals</i> |                 |                    |                    |                                                    |                                                            |                                         |                                                 |
| CAnurserySTD               | 0.211           | 0.052              | 0.059              | <0.01                                              | <i>5.28</i>                                                | <0.01                                   | <i>6.84</i>                                     |
| FLnurserySTD               | 0.071           | 0.021              | 0.023              | <0.01                                              | <i>1.77</i>                                                | <0.01                                   | <i>2.61</i>                                     |
| MlnurserySTD               | 0.059           | 0.032              | 0.033              | <0.01                                              | <i>1.47</i>                                                | <0.01                                   | <i>3.80</i>                                     |
| NJnurserySTD               | 0.085           | 0.036              | 0.037              | <0.01                                              | <i>2.14</i>                                                | <0.01                                   | <i>4.29</i>                                     |
| ORnurserySTD               | 0.017           | 0.010              | 0.010              | <0.01                                              | <i>0.44</i>                                                | <0.01                                   | <i>1.17</i>                                     |
| TNnurserySTD               | 0.117           | 0.045              | 0.046              | <0.01                                              | <i>2.93</i>                                                | <0.01                                   | <i>5.31</i>                                     |
| <i>Cucurbits</i>           |                 |                    |                    |                                                    |                                                            |                                         |                                                 |
| FLcucumberSTD              | 0.053           | 0.017              | 0.018              | <0.01                                              | <i>1.33</i>                                                | <0.01                                   | <i>2.09</i>                                     |

<sup>1</sup> based on the sheepshead minnow LC50 of 1430 ppb

<sup>2</sup> based on the mysid shrimp LC50 of 0.04 ppb

<sup>3</sup> based on the mysid shrimp NOAEC of 0.0087 ppb

<sup>4</sup> based on sheepshead minnow NOAEC 48 ppb.

\* Values in red exceed the LOC for Acute listed species (RQ ≥ 0.05)

\*\* Values in red and italics exceed the LOC for acute listed species (RQ ≥ 0.05), acute restricted use (RQ ≥ 0.1), and acute non-listed species (RQ ≥ 0.5)

\*\*\* Values in red and bold exceed the LOC for Chronic Risk (RQ > 1.0) to listed and non-listed species

## Aquatic Plants

**Table 5-4. RQs for Emamectin benzoate for Aquatic Plants from use on Ornamentals and Cucurbits**

| Scenario                  | Peak EEC (ppb) | Non-Vascular Plant RQ <sup>1</sup> (EEC/EC50) | Vascular Plant RQ <sup>2</sup> (EEC/NOEC) |
|---------------------------|----------------|-----------------------------------------------|-------------------------------------------|
| <i>Outdoor Ornamental</i> |                |                                               |                                           |
| CAnurserySTD              | 0.211          | 0.05                                          | <0.01                                     |
| FLnurserySTD              | 0.071          | 0.02                                          | <0.01                                     |
| MlnurserySTD              | 0.059          | 0.02                                          | <0.01                                     |
| NJnurserySTD              | 0.085          | 0.02                                          | <0.01                                     |
| ORnurserySTD              | 0.017          | <0.01                                         | <0.01                                     |
| TNnurserySTD              | 0.117          | 0.03                                          | <0.01                                     |
| <i>Cucurbit</i>           |                |                                               |                                           |
| FLcucumberSTD             | 0.053          | 0.01                                          | <0.01                                     |

<sup>1</sup> based on the green algae EC50 of >3.9 ppb

<sup>2</sup> based on the duckweed EC50 of >94 ppb

## Birds and Mammals following Acute and Chronic Exposure

**Table 5-5. Upper Bound Kenaga, Acute Avian Dose-Based Risk Quotients**

| Size Class<br>(grams) | Adjusted LD50 | EECs and RQs                             |      |            |      |                                    |      |                                         |      |           |       |
|-----------------------|---------------|------------------------------------------|------|------------|------|------------------------------------|------|-----------------------------------------|------|-----------|-------|
|                       |               | Short Grass                              |      | Tall Grass |      | Broadleaf Plants/<br>Small Insects |      | Fruits/Pods/<br>Seeds/<br>Large Insects |      | Granivore |       |
|                       |               | EEC                                      | RQ   | EEC        | RQ   | EEC                                | RQ   | EEC                                     | RQ   | EEC       | RQ    |
|                       |               | Maximum Application rate 0.015 lb a.i./A |      |            |      |                                    |      |                                         |      |           |       |
| 20                    | 23.88         | 17.89                                    | 0.75 | 8.20       | 0.34 | 10.06                              | 0.42 | 1.12                                    | 0.05 | 0.25      | 0.01  |
| 100                   | 30.41         | 10.20                                    | 0.34 | 4.67       | 0.15 | 5.74                               | 0.19 | 0.64                                    | 0.02 | 0.14      | <0.01 |
| 1000                  | 42.95         | 4.57                                     | 0.11 | 2.09       | 0.05 | 2.57                               | 0.06 | 0.29                                    | 0.01 | 0.06      | <0.01 |

\*Values in red exceed the LOC for acute listed species (RQ  $\geq 0.1$ )

\*\*Values in red and italics exceed the LOC for acute listed species (RQ  $\geq 0.1$ ) and acute restricted use (RQ  $\geq 0.2$ )

\*\*\*Values in red, bold, and italics exceed the LOC for acute listed species (RQ  $\geq 0.1$ ), acute restricted use (RQ  $\geq 0.2$ ), and acute non-listed species (RQ  $\geq 0.5$ )

**Table 5-6. Upper Bound Kenaga, Subacute Avian Dietary Based Risk Quotients.**

| LC50                                            | EECs and RQs |      |            |      |                                 |      |                                   |       |
|-------------------------------------------------|--------------|------|------------|------|---------------------------------|------|-----------------------------------|-------|
|                                                 | Short Grass  |      | Tall Grass |      | Broadleaf Plants/ Small Insects |      | Fruits/Pods/ Seeds/ Large Insects |       |
|                                                 | EEC          | RQ   | EEC        | RQ   | EEC                             | RQ   | EEC                               | RQ    |
| <i>Maximum Application rate 0.015 lb a.i./A</i> |              |      |            |      |                                 |      |                                   |       |
| 570                                             | 15.71        | 0.03 | 7.20       | 0.01 | 8.83                            | 0.02 | 0.98                              | <0.01 |

Size class not used for dietary risk quotients

**Table 5-7. Upper Bound Kenaga, Chronic Avian Dietary Based Risk Quotients.**

| NOAEC (ppm)                                     | EECs and RQs |      |            |      |                                 |      |                                   |      |
|-------------------------------------------------|--------------|------|------------|------|---------------------------------|------|-----------------------------------|------|
|                                                 | Short Grass  |      | Tall Grass |      | Broadleaf Plants/ Small Insects |      | Fruits/Pods/ Seeds/ Large Insects |      |
|                                                 | EEC          | RQ   | EEC        | RQ   | EEC                             | RQ   | EEC                               | RQ   |
| <i>Maximum Application rate 0.015 lb a.i./A</i> |              |      |            |      |                                 |      |                                   |      |
| 40                                              | 15.71        | 0.39 | 7.20       | 0.18 | 8.83                            | 0.22 | 0.98                              | 0.02 |

Size class not used for dietary risk quotients



Table 5-8. Upper Bound Kenaga, Acute Mammalian Dose-Based Risk Quotients.

| Size Class (grams) | Adjusted LD50 | EECs and RQs                             |      |            |      |                                 |      |                                   |      |           |       |
|--------------------|---------------|------------------------------------------|------|------------|------|---------------------------------|------|-----------------------------------|------|-----------|-------|
|                    |               | Short Grass                              |      | Tall Grass |      | Broadleaf Plants/ Small Insects |      | Fruits/Pods/ Seeds/ Large Insects |      | Granivore |       |
|                    |               | EEC                                      | RQ   | EEC        | RQ   | EEC                             | RQ   | EEC                               | RQ   | EEC       | RQ    |
|                    |               | Maximum Application rate 0.015 lb a.i./A |      |            |      |                                 |      |                                   |      |           |       |
| 15                 | 25.92         | 14.97                                    | 0.58 | 6.86       | 0.26 | 8.42                            | 0.32 | 0.94                              | 0.04 | 0.21      | 0.01  |
| 35                 | 20.97         | 10.35                                    | 0.49 | 4.74       | 0.23 | 5.82                            | 0.28 | 0.65                              | 0.03 | 0.14      | 0.01  |
| 1000               | 9.07          | 2.40                                     | 0.26 | 1.10       | 0.12 | 1.35                            | 0.15 | 0.15                              | 0.02 | 0.03      | <0.01 |

\* Values in red exceed the LOC for acute listed species (RQ  $\geq 0.1$ )

\*\* Values in red and italics exceed the LOC for acute listed species (RQ  $\geq 0.1$ ) and acute restricted use (RQ  $\geq 0.2$ )

\*\*\* Values in red, bold, and italics exceed the LOC for acute listed species (RQ  $\geq 0.1$ ), acute restricted use (RQ  $\geq 0.2$ ), and acute non-listed species (RQ  $\geq 0.5$ )

Table 5-9. Upper Bound Kenaga, Chronic Mammalian Dietary Based Risk Quotients.

| NOAEC (ppm)                                     | EECs and RQs |             |            |      |                                 |      |                                   |      |
|-------------------------------------------------|--------------|-------------|------------|------|---------------------------------|------|-----------------------------------|------|
|                                                 | Short Grass  |             | Tall Grass |      | Broadleaf Plants/ Small Insects |      | Fruits/Pods/ Seeds/ Large Insects |      |
|                                                 | EEC          | RQ          | EEC        | RQ   | EEC                             | RQ   | EEC                               | RQ   |
| <i>Maximum Application rate 0.015 lb a.i./A</i> |              |             |            |      |                                 |      |                                   |      |
| 12                                              | 15.71        | <b>1.31</b> | 7.20       | 0.60 | 8.83                            | 0.74 | 0.98                              | 0.08 |

Size class not used for dietary risk quotients

\* Values in red and bold exceed the LOC for Chronic Risk (RQ > 1.0) to listed and non-listed species

Table 5-10. Upper Bound Kenaga, Chronic Mammalian Dose-Based Risk Quotients

| Table 5-16: Upper Bound (High) On-Use Maximum Use Based Risk Quotients |                |              |       |            |      |                                 |      |                                   |      |           |      |
|------------------------------------------------------------------------|----------------|--------------|-------|------------|------|---------------------------------|------|-----------------------------------|------|-----------|------|
| Size Class (grams)                                                     | Adjusted NOAEL | EECs and RQs |       |            |      |                                 |      |                                   |      |           |      |
|                                                                        |                | Short Grass  |       | Tall Grass |      | Broadleaf Plants/ Small Insects |      | Fruits/Pods/ Seeds/ Large Insects |      | Granivore |      |
|                                                                        |                | EEC          | RQ    | EEC        | RQ   | EEC                             | RQ   | EEC                               | RQ   | EEC       | RQ   |
| Maximum Application rate 0.015 lb a.i./A                               |                |              |       |            |      |                                 |      |                                   |      |           |      |
| 15                                                                     | 1.32           | 14.97        | 11.35 | 6.86       | 5.20 | 8.42                            | 6.39 | 0.94                              | 0.71 | 0.21      | 0.16 |
| 35                                                                     | 1.07           | 10.35        | 9.70  | 4.74       | 4.45 | 5.82                            | 5.46 | 0.65                              | 0.61 | 0.14      | 0.13 |
| 1000                                                                   | 0.46           | 2.40         | 5.20  | 1.10       | 2.38 | 1.35                            | 2.92 | 0.15                              | 0.32 | 0.03      | 0.07 |

\* Values in red and bold exceed the LOC for Chronic Risk (RQ > 1.0) to listed and non-listed species

Terrestrial Plants – No Data; TerrPlant not run.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

**MEMORANDUM**

**DATE:** March 1, 2012

**SUBJECT:** Emamectin Benzoate. Occupational Exposure Assessment for a Proposed New Use on Cucurbit Vegetables (Crop Group 9).

|                             |                                              |
|-----------------------------|----------------------------------------------|
| <b>PC Code:</b> 122806      | <b>DP Barcode:</b> 393839                    |
| <b>Decision No.:</b> 452138 | <b>Registration No.:</b> 100-904             |
| <b>Petition No.:</b> 1E7904 | <b>Regulatory Action:</b> Section 3          |
| <b>Case No.:</b> NA         | <b>Risk Assessment Type:</b> Single Chemical |
| <b>TXR No.:</b> NA          | <b>CAS No.:</b> 155569-91-8                  |
| <b>MRID No.:</b> NA         | <b>40 CFR:</b> §180.505                      |

**FROM:** Nancy J. Tsaor, Chemist  
Risk Assessment Branch 3  
Health Effects Division (7509P)

**THROUGH:** Barry O'Keefe, ORE Team Leader  
Risk Assessment Branch 3  
Health Effects Division (7509P)

**TO:** Barbara Madden RM 05  
Risk Integration Minor Use and Emergency Branch  
and  
Andrew Ertman  
Insecticide and Rodenticide Branch  
Registration Division (7505P)

The Registration Division (RD) requested that the Health Effects Division (HED) conduct an occupational exposure and risk assessment for the newly proposed foliar use of emamectin benzoate on cucurbit vegetables (crop group 9). Note: This memorandum was reviewed by the Exposure Science Advisory Council (ExpoSAC) on 03/01/2012.

## 1.0 EXECUTIVE SUMMARY

Emamectin benzoate is a semi-synthetic avermectin, consisting of two active homologous compounds (a benzoate salt mixture of a minimum of 90% 4'-epi-methylamino-4'-deoxyavermectin B<sub>1a</sub> and a maximum of 10% 4'-epi-methylamino-4'-deoxyavermectin B<sub>1b</sub>). Emamectin benzoate is an insecticide/miticide developed for the control of *lepidopteran* insects.

The Interregional Research Project No. 4 (IR-4) is proposing a new use on cucurbit vegetables. Proclaim® Insecticide (EPA Reg. No. 100-904) is a water soluble granule formulation (SG) containing 5.0% active ingredient (ai), emamectin benzoate, by weight.

Based on application rate and label information, exposure is expected to occur for short- and intermediate-term durations. Chronic exposure is not expected for the proposed use patterns.

### Proposed Use Profile

Proclaim® Insecticide may be applied as a foliar spray via aircraft (except in New York State) or groundboom. Chemigation is prohibited. For high pest infestations, the maximum single application rate is 4.8 oz/A (0.015 lb ai/A). Applications may be repeated at a 7-day interval to maintain control, up to a maximum seasonal application rate of 28.8 oz/A (0.090 lb ai/A/season).

### Hazard Concerns

All endpoints were selected from a 15-day oral neurotoxicity study in the mouse. Dermal and inhalation exposures were combined and then compared to the short-term oral NOAEL of 0.075 mg/kg/day. The endpoint includes moribund sacrifices, clinical signs of neurotoxicity, decreases in body weight and food consumption and histopathological lesions in the sciatic nerve (LOAEL of 0.1 mg/kg/day). The dermal absorption rate of 1.8% used in this assessment is based on a dermal absorption study in the Rhesus monkey, while no inhalation absorption rate is used because toxicity by the inhalation route is considered to be equivalent to the estimated toxicity of the oral route of exposure. The level of concern (LOC) for short-term exposure is a margin of exposure (MOE) less than 300 [uncertainty factors (UFs) include: 10X for interspecies extrapolation, 10X for intraspecies variation; and 3X modifying factor (UF<sub>M</sub>) to account for the steepness of the dose-response curve and the severity of effects at the LOAEL (death and neuropathology)]. The LOC for intermediate-term exposure is an MOE less than 1000, which includes a 10X UF<sub>M</sub> (rather than 3X) to account for the additional uncertainty of using a short-term study for an intermediate-term risk assessment. Emamectin benzoate is classified as "Not likely to be Carcinogenic to Humans" based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.

Emamectin benzoate is acutely toxic via the oral (Toxicity Category IV) and inhalation (Toxicity Category IV) routes. Via the dermal route, emamectin benzoate is Toxicity Category III. For dermal and eye irritation, it is Toxicity Category III and IV, respectively. However, emamectin benzoate is not a dermal sensitizer.

### Residential Exposures and Risk Estimates

Residential exposures are not assessed in this document because emamectin benzoate is a



Restricted Use Pesticide (RUP) and limited to use by certified applicators in commercial areas. Currently, there are no registered products that would lead to residential handler or post-application exposure.

#### Occupational Handler Exposures and Risk Estimates

There is potential for short- and intermediate-term occupational exposure to emamectin benzoate during handling activities (e.g. mixing, loading, application).

For short-term handler exposure, only one scenario results in an MOE of concern (less than the LOC of 300). The mixing/loading scenario for aerial application results in an MOE of 88 at baseline and 120 with the required personal protective equipment (PPE) as indicated on the label. The PPE includes double layer clothing and chemical-resistant gloves. With a suggested mitigation technique of water soluble packaging, the MOE is 11,000 which is greater than the LOC and not of concern.

For intermediate-term exposure, all mixing/loading scenarios are of concern (less than the LOC of 1000) with the proposed formulation. At baseline, the MOEs range from 88 to 380. With the required dermal PPE (double layer clothing and chemical-resistant gloves), the MOEs range from 120 to 520. With a suggested mitigation of water soluble packaging, dermal and inhalation exposures would significantly decrease, resulting in MOEs greater than the LOC (ranging from 2,100 to 12,000).

#### Occupational Post-Application Exposures and Risk Estimates

There is a potential for short- and intermediate-term occupational exposure during post-application activities. Based on a quantitative post-application assessment of common agricultural practices for short-term exposure durations, the post-application MOEs are not of concern (MOEs  $\geq 300$ , ranging from 520 to 11,000) on day 0 (12 hours after application). However, since the intermediate-term post-application risk estimates were of concern (MOEs  $< 1000$ ) on day 0 (12 hours following application), the 12-hour REI on the proposed label is unacceptable and an REI of 7 days is recommended for cucurbit vegetables.

#### Review of Human Research

This risk assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide or other chemical. These studies, which comprise the Pesticide Handlers Exposure Database (PHED) and the Agricultural Handler Exposure Task Force (AHETF), have been determined to require a review of their ethical conduct, have received that review, and have been determined to be ethical.

## **2.0 HAZARD CHARACTERIZATION**

The acute toxicity for the technical emamectin benzoate formulation (EPA Reg. No. 100-1270) used in this proposed product (EPA Reg. No. 100-904) is summarized in Table 1.



| Table 1. Acute Toxicity Profile – Emamectin Benzoate Technical II (EPA Reg. No. 100-1270). |                                   |          |                                               |                   |
|--------------------------------------------------------------------------------------------|-----------------------------------|----------|-----------------------------------------------|-------------------|
| Guideline No.                                                                              | Study Type                        | MRID     | Results                                       | Toxicity Category |
| 870.1100                                                                                   | Acute oral - Rats                 | 47002104 | LD <sub>50</sub> for L-656,748-038 = 53 mg/kg | II                |
| 870.1200                                                                                   | Acute dermal - Rabbits (EC)       | 47002106 | LD <sub>50</sub> > 2.0 g/kg                   | III               |
| 870.1300                                                                                   | Acute inhalation - Rats           | 47002107 | LC <sub>50</sub> 0.10 mg/L                    | II                |
| 870.2400                                                                                   | Acute eye irritation - Rabbits    | 47002108 | Severe irritation                             | III               |
| 870.2500                                                                                   | Acute dermal irritation - Rabbits | 47002109 | No dermal irritation                          | IV                |
| 870.2600                                                                                   | Skin sensitization - Guinea pigs  | 47002110 | Not a dermal sensitizer                       | Negative          |

Table 2 summarizes the selected endpoints for occupational risk assessment.

| Table 2. Summary of Toxicological Doses and Endpoints for Emamectin Benzoate for Use in Occupational Human Health Risk Assessments. |                                                                 |                                                                        |                                      |                                                                                                                                                                                                                                    |
|-------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|------------------------------------------------------------------------|--------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Exposure/Scenario                                                                                                                   | Point of Departure                                              | Uncertainty Factors                                                    | Level of Concern for Risk Assessment | Study and Toxicological Effects                                                                                                                                                                                                    |
| Dermal Short-Term (1-30 days)                                                                                                       | NOAEL = 0.075 mg/kg/day (dermal absorption rate = 1.8%)         | UF <sub>A</sub> = 10X<br>UF <sub>H</sub> = 10X<br>UF <sub>M</sub> = 3X | Occupational LOC<br>MOE = 300        | <b>15-day oral neurotoxicity – mouse</b><br>LOAEL = 0.1 mg/kg/day based on moribund sacrifices, clinical signs of neurotoxicity, decreases in body weight and food consumption and histopathological lesions in the sciatic nerve. |
| Dermal Intermediate-Term (1-6 months)                                                                                               | NOAEL = 0.075 mg/kg/day (dermal absorption rate = 1.8%)         | UF <sub>A</sub> = 10X<br>UF <sub>H</sub> = 10X<br>UF <sub>M</sub> = 3X | Occupational LOC<br>MOE = 1000       | <b>15-day oral neurotoxicity – mouse</b><br>LOAEL = 0.1 mg/kg/day based on moribund sacrifices, clinical signs of neurotoxicity, decreases in body weight and food consumption and histopathological lesions in the sciatic nerve. |
| Inhalation Short-Term (1-30 days)                                                                                                   | NOAEL = 0.075 mg/kg/day (assumed equivalent to oral absorption) | UF <sub>A</sub> = 10X<br>UF <sub>H</sub> = 10X<br>UF <sub>M</sub> = 3X | Occupational LOC<br>MOE = 300        | <b>15-day oral neurotoxicity – mouse</b><br>LOAEL = 0.1 mg/kg/day based on moribund sacrifices, clinical signs of neurotoxicity, decreases in body weight and food consumption and histopathological lesions in the sciatic nerve. |

**Table 2. Summary of Toxicological Doses and Endpoints for Emamectin Benzoate for Use in Occupational Human Health Risk Assessments.**

| Exposure/Scenario                         | Point of Departure                                                                                                                                            | Uncertainty Factors                                                     | Level of Concern for Risk Assessment | Study and Toxicological Effects                                                                                                                                                                                             |
|-------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|--------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Inhalation Intermediate-Term (1-6 months) | NOAEL = 0.075 mg/kg/day (assumed equivalent to oral absorption)                                                                                               | UF <sub>A</sub> = 10X<br>UF <sub>H</sub> = 10X<br>UF <sub>M</sub> = 10X | Occupational LOC<br>MOE = 1000       | 15-day oral neurotoxicity – mouse<br>LOAEL = 0.1 mg/kg/day based on moribund sacrifices, clinical signs of neurotoxicity, decreases in body weight and food consumption and histopathological lesions in the sciatic nerve. |
| Cancer (oral, dermal, inhalation)         | Classification: “Not likely to be Carcinogenic to Humans” based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies. |                                                                         |                                      |                                                                                                                                                                                                                             |

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk estimate associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies). UF<sub>M</sub> = Modifying factor to account for the steepness of the dose-response curve, severity of effects at the LOAEL (death and neuropathology), and the use of a short-term study for intermediate-term risk assessment. MOE = margin of exposure. LOC = level of concern. Dermal absorption of 1.8% is assumed.

### 3.0 PROPOSED USE PATTERNS

Proclaim® Insecticide controls the larval stages (worms/caterpillars) of several lepidopteran species. Proclaim® Insecticide has contact activity, but is most efficacious when ingested by the pest. Shortly after exposure, affected larvae are paralyzed, stop feeding, and subsequently die after 2-4 days.

Proclaim® Insecticide may be applied as a foliar spray via aircraft (except in New York State) or groundboom. Chemigation is prohibited. For high pest infestations, the maximum single application rate is 4.8 oz/A (0.015 lb ai/A). Applications may be repeated at a 7-day interval to maintain control, up to a maximum seasonal application rate of 28.8 oz/A (0.090 lb ai/A/season). The proposed label is summarized in Table 3.

**Table 3. Use Profile for Proposed Emamectin Benzoate Uses.**

| Proclaim® Insecticide<br>EPA Reg. No. 100-904<br>water soluble granule (SG), 5.0% ai by weight |                       |                                 |         |
|------------------------------------------------------------------------------------------------|-----------------------|---------------------------------|---------|
| Use Site                                                                                       | Application Equipment | Single Maximum Application Rate |         |
|                                                                                                |                       | oz/A                            | lb ai/A |
| Cucurbit Vegetables (CG9)                                                                      | Groundboom, Aerial    | 4.8                             | 0.015   |



#### **4.0 RESIDENTIAL (NON-OCCUPATIONAL) EXPOSURE**

Residential exposures are not assessed in this document because emamectin benzoate is a Restricted Use Pesticide (RUP) and limited to use by certified applicators in commercial areas. Currently, there are no registered products that would lead to residential handler or post-application exposure.

##### Residential Bystander Post-Application Inhalation Exposure

Based on the Agency's current practices, a quantitative post-application inhalation exposure assessment was not performed for emamectin benzoate at this time because the chemical has low vapor pressure ( $3.0 \times 10^{-8}$  mm Hg at 21 °C) and is applied at a low rate (0.015 lb ai/A). However, volatilization of pesticides may be a potential source of post-application inhalation exposure to individuals nearby to pesticide applications. The Agency sought expert advice and input on issues related to volatilization of pesticides from its Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (SAP) in December 2009. The Agency received the SAP's final report on March 2, 2010 (<http://www.epa.gov/scipoly/SAP/meetings/2009/120109meeting.html>) and is in the process of evaluating the SAP report. The Agency may, as appropriate, develop policies and procedures to identify the need for and, subsequently, the way to incorporate post-application inhalation exposure into the Agency's risk assessments. If new policies or procedures are put into place, the Agency may revisit the need for a quantitative post-application inhalation exposure assessment for emamectin benzoate.

##### Spray Drift

Spray drift is always a potential source of exposure to residents nearby to spraying operations. This is particularly the case with aerial application, but, to a lesser extent, could also be a potential source of exposure from the ground application method employed for the previously-registered uses of emamectin benzoate. The Agency has been working with the Spray Drift Task Force, EPA Regional Offices, and State Lead Agencies for pesticide regulation and other parties to develop the best spray drift management practices. The Agency is now requiring interim mitigation measures for aerial applications that must be placed on product labels/labeling. The Agency has completed its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, and is developing a policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air, orchard airblast, and ground hydraulic methods. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift and risk estimates associated with aerial as well as other application types where appropriate.

#### **5.0 OCCUPATIONAL EXPOSURE/RISK ESTIMATES PATHWAY**

Occupational handler exposure to emamectin benzoate is expected for individuals involved in foliar applications to cucurbit vegetables (mixing, loading, flagging, and applying).

Additionally, agricultural workers performing typical post-application activities such as scouting,



irrigation, and harvesting are likely to receive exposure to emamectin benzoate residues based on the repeated use pattern to maintain control of pests.

## 5.1 Occupational Handler

Proclaim® Insecticide may be applied as a foliar spray via aircraft (except in New York State) or groundboom. The proposed use pattern is summarized in Table 2. Handler exposure is expected to be short- or intermediate-term based on information provided on the proposed label. Table 3 summarizes the PPE required on the proposed label.

| Table 4. Required PPE on Label (EPA Reg. No. 100-904).                                                                                                                 |                                                                                                                                                                                                                                                                                              |                                                                                                                                                                               |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Ground Application (except airblast sprayers)                                                                                                                          |                                                                                                                                                                                                                                                                                              |                                                                                                                                                                               |
| Applicators, Mixers, Loaders, Other Handlers                                                                                                                           | Long-sleeved shirt and long pants<br>Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber<br>Shoes plus socks                                                                                                                |                                                                                                                                                                               |
| Aerial Application                                                                                                                                                     |                                                                                                                                                                                                                                                                                              |                                                                                                                                                                               |
| Mixers, Loaders, Other Handlers                                                                                                                                        | Coveralls over long-sleeved shirt and long pants<br>Shoes plus socks<br>Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber<br>Dust/Mist-filtering respirator or a NIOSH-approved respirator with any N, R, P, or HE filter |                                                                                                                                                                               |
| Applicators (ENCLOSED Cockpit)<br>NOTE: Once inside the cockpit, applicator must remove gloves and store them in a chemical-resistant container such as a plastic bag. | While inside the cockpit must wear:<br>Long-sleeved shirt and long pants<br>Shoes plus socks                                                                                                                                                                                                 | When entering or leaving the cockpit must also wear:<br>Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber. |
| Flaggers                                                                                                                                                               | Long-sleeved shirt and long pants<br>Shoes plus socks<br>Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber.                                                                                                               |                                                                                                                                                                               |

The quantitative exposure/risk assessment developed for occupational handlers is based on the following exposure scenarios:

### Mixer/Loaders

1. Mixing/loading dry flowables to support groundboom applications,
2. Mixing/loading dry flowables to support aerial applications,

### Flaggers

3. Flagging to support aerial application,

### Applicators

4. Applying sprays with groundboom equipment, and

## 5. Applying sprays with aerial equipment.

### 5.1.1 Data and Assumptions for Handler Exposure Scenarios

#### Unit Exposures

No chemical-specific handler exposure data were submitted in support of this proposed use of emamectin benzoate on cucurbit vegetables. To assess handler exposures for regulatory actions when chemical-specific monitoring data are not available, HED relies on the most scientifically-reliable surrogate data currently available from various sources such as PHED, AHETF, and the Outdoor Residential Exposure Task Force (ORETF). Some of these data, such as the industry task force data, are compensatory, subject to the data protection provisions of FIFRA. HED policy on use of surrogate data is described in more detail on the Agency's website (<http://www.epa.gov/pesticides/science/handler-exposure-data.html>). Scenario-specific surrogate exposure data, including their sources, are presented in the "Occupational Pesticide Handler Unit Exposure Surrogate Reference Table" (<http://www.epa.gov/pesticides/science/handler-exposure-table.pdf>).

#### Area/Amount Treated

Based on HED ExpoSAC Policy No. 9.1, the area treated in a day was assumed to be:

- 80 acres for mixing/loading to support groundboom applications,
- 350 acres for mixing/loading to support aerial applications,
- 350 acres for flagging to support aerial treatment,
- 80 acres for applying with groundboom equipment, and
- 350 acres for applying with aerial equipment.

#### Application Rate

For high pest infestations, the maximum single application rate is 4.8 oz/A (0.015 lb ai/A). Applications may be repeated at a 7-day interval to maintain control, up to a maximum seasonal application rate of 28.8 oz/A (0.090 lb ai/A/season).

#### Body Weight

The average adult body weight of 80 kg was used for estimating short- and intermediate-term dermal and inhalation dose because the selected toxicological PoDs are not based on developmental effects.

#### Absorption Factors

- Since the short- and intermediate-term dermal endpoints are based on an oral study, a dermal absorption factor of 1.8% is used to estimate dermal exposure for both durations.
- Since the short- and intermediate-term inhalation endpoint was based on an oral study and no inhalation absorption data are available, toxicity by the inhalation route is considered to be equivalent to the estimated toxicity by the oral route of exposure.

#### Equations and Calculations

##### ***Daily Dose***



Daily dose (dermal and inhalation) is calculated by normalizing the daily exposure (dermal or inhalation) value by body weight and accounting for absorption factors.

$$\text{Average Daily Dose (mg/kg/day)} = \text{Daily Exposure (mg ai/day)} \times \frac{\{\text{Absorption Factor (\%/100)}\}}{\text{Body Weight (kg)}}$$

Where:

Average Daily Dose= Absorbed dose received from exposure to a pesticide in a given scenario (mg pesticide active ingredient/kg body weight/day),  
 Daily Exposure = Amount (mg ai/day) deposited on the surface of the skin that is available for dermal absorption or amount inhaled that is available for inhalation absorption,  
 Absorption Factor = A measure of the amount of chemical that crosses a biological boundary such as the skin or lungs, and  
 Body Weight = Body weight determined to represent the population of interest in a risk assessment.

### ***Margin of Exposure (MOE)***

The daily inhalation dose received by occupational handlers was compared to the appropriate PoD (i.e. NOAELs) to assess the risk to occupational handlers. All MOE values were calculated using the following formula:

$$\text{MOE} = \frac{\text{NOAEL (mg/kg/day)}}{\text{Average Daily Dose (mg/kg/day)}}$$

Where:

MOE = Margin of exposure value used by HED to represent risk or how close a chemical exposure is to being a concern (unitless),  
 ADD = Average daily dose (ADD) is absorbed dose received from exposure to pesticide, and  
 NOAEL = Dose level in a toxicity study, where no observed adverse effects occurred in the study.

### ***Combined Risk Estimates***

Dermal and inhalation risk estimates were combined in this assessment, since the toxicological effects for the dermal and inhalation routes were the same. Since short- and intermediate-term dermal and inhalation PoDs were the same, risk estimates were combined using the following formula:

$$\text{Total MOE} = \text{NOAEL}/(\text{Dermal Dose} + \text{Inhalation Dose})$$

## **5.1.2 Handler Exposure and Risk Estimates**

Summaries of the short- and intermediate-term risk estimates for occupational handlers are included in Tables 5 and 6. The maximum application rate for each exposure scenario is presented as the worst case scenario.

### **Short-Term Exposure Duration**

At baseline, without any required PPE, all handler scenarios (mixer/loader, applicator, and



flagger) resulted in short-term combined (dermal + inhalation) MOEs greater than the short-term LOC of 300, except for mixing/loading dry flowables for aerial application (MOE = 88). At the required levels of PPE as summarized in Table 4 (namely, double layer clothing and chemical-resistant gloves), the scenario of mixing/loading dry flowables for aerial application remains of concern (see Table 6, MOE = 120).

Mitigation via water-soluble packets (WSPs) would significantly decrease both dermal and inhalation exposure during mixing/loading activities for aerial applications, resulting in an MOE of 2,700 (see Table 6).

#### Intermediate-Term Exposure Duration

At baseline, two scenarios are less than the intermediate-term LOC of 1000: (1) mixing/loading dry flowables for groundboom (MOE = 380) and (2) mixing/loading dry flowables for aerial application (MOE = 88). At the required levels of PPE as summarized in Table 4 (namely, double layer clothing and chemical-resistant gloves), both scenarios still result in combined MOEs less than the LOC (see Table 6, MOEs = 520 and 120, respectively).

Mitigation via water-soluble packets (WSPs) would significantly decrease both dermal and inhalation exposure during mixing/loading activities for ground and aerial applications, resulting in MOEs of 12,000 and 2,700, respectively. Table 6 shows the risk estimates for occupational handlers with added engineering controls of WSPs.

**Table 5. Baseline Emamectin Benzoate Short- and Intermediate Term Occupational Exposures and Risk Estimates for Cucurbit Vegetable Use.**

| Exposure Scenario                                          | Applica-<br>tion<br>Rate <sup>a</sup> | Area<br>Treated<br>Daily <sup>b</sup> | Baseline<br>Dermal<br>UEs <sup>c</sup> | Baseline<br>Inhalation<br>UEs <sup>c</sup> | Baseline<br>Dermal<br>Dose <sup>d</sup> | Baseline<br>Inhalation<br>Dose <sup>d</sup> | Total<br>Dose <sup>e</sup> | Baseline<br>Dermal<br>MOE   | Baseline<br>Inhalation<br>MOE | Baseline<br>Total<br>MOE <sup>f</sup> |
|------------------------------------------------------------|---------------------------------------|---------------------------------------|----------------------------------------|--------------------------------------------|-----------------------------------------|---------------------------------------------|----------------------------|-----------------------------|-------------------------------|---------------------------------------|
|                                                            | lb ai/A                               | acres                                 | µg/lb ai                               |                                            | mg/kg/day                               |                                             |                            | ST LOC = 300, IT LOC = 1000 |                               |                                       |
| Mixer/Loader                                               |                                       |                                       |                                        |                                            |                                         |                                             |                            |                             |                               |                                       |
| Mixing/Loading Dry Flowables<br>for Groundboom Application | 0.0150                                | 80                                    | 227                                    | 8.96                                       | 0.000061                                | 0.00013                                     | 0.00020                    | 1,200                       | 560                           | 380                                   |
| Mixing/Loading Dry Flowables<br>for Aerial Application     | 0.0150                                | 350                                   | 227                                    | 8.96                                       | 0.00027                                 | 0.00059                                     | 0.00086                    | 280                         | 130                           | 88                                    |
| Flagger                                                    |                                       |                                       |                                        |                                            |                                         |                                             |                            |                             |                               |                                       |
| Flagging for Aerial Application                            | 0.0150                                | 350                                   | 11                                     | 0.35                                       | 0.000013                                | 0.000023                                    | 0.000036                   | 5,800                       | 3,300                         | 2,100                                 |
| Applicator                                                 |                                       |                                       |                                        |                                            |                                         |                                             |                            |                             |                               |                                       |
| Applying Sprays via<br>Groundboom Equipment                | 0.0150                                | 80                                    | 78.6                                   | 0.34                                       | 0.000021                                | 0.000051                                    | 0.000026                   | 3,500                       | 15,000                        | 2,800                                 |
| Applying Sprays via Aerial<br>Equipment                    | 0.0150                                | 350                                   | 5                                      | 0.068                                      | 0.0000059                               | 0.0000045                                   | 0.000010                   | 13,000                      | 17,000                        | 7,200                                 |

a Application Rates based on proposed uses for emamectin benzoate (Proclaim® Insecticide, EPA Reg. No. 100-904).

b Acres Treated Per Day is taken from Exposure Science Advisory Council (ExpoSAC) Policy No. 9.1.

c UEs = Unit Exposures based on PHED Version 1.1, ORETF, or AHETF data. Baseline = no gloves, no respirator.

d Dose (mg/kg/day) = daily unit exposure ( $\mu\text{g/lb ai}$ ) x application rate (lb ai/acre) x amount handled /day (acres/day) x conversion factor (1 mg/1,000  $\mu\text{g}$ ) x absorption factor (%) / body weight (80 kg).

e Total Dose = Dermal Dose (mg/kg/day) + Inhalation Dose (mg/kg/day).

f Total MOE = NOAEL / Total Dose (mg/kg/day). ST/IT Dermal/Inhalation NOAEL = 0.075 mg/kg/day. ST level of concern = 300. IT level of concern = 1000.

**Table 6. Mitigated Emamectin Benzoate Short- and Intermediate Term Occupational Exposures and Risk Estimates for Cucurbit Vegetable Use.**

| Exposure Scenario                                                                                                                              | Applic-<br>ation<br>Rate <sup>a</sup> | Area<br>Treated<br>Daily <sup>b</sup> | Dermal<br>UEs <sup>c</sup> | Inhalation<br>UEs <sup>c</sup> | Dermal<br>Dose <sup>d</sup> | Inhalation<br>Dose <sup>d</sup> | Total<br>Dose <sup>e</sup> | Dermal<br>MOE               | Inhalation<br>MOE | Total<br>MOE <sup>f</sup> |
|------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|---------------------------------------|----------------------------|--------------------------------|-----------------------------|---------------------------------|----------------------------|-----------------------------|-------------------|---------------------------|
|                                                                                                                                                | lb ai/A                               | acres                                 | µg/lb ai                   |                                | mg/kg/day                   |                                 |                            | ST LOC = 300, IT LOC = 1000 |                   |                           |
| Mixer/Loader – Risk Estimates with Required Dermal PPE (Listed on Existing Registered Label: double layer clothing, chemical-resistant gloves) |                                       |                                       |                            |                                |                             |                                 |                            |                             |                   |                           |
| Mixing/Loading Dry Flowables<br>for Groundboom Application                                                                                     | 0.0150                                | 80                                    | 41.2                       | 8.96                           | 0.000011                    | 0.00013                         | 0.00015                    | 6,700                       | 560               | 520                       |
| Mixing/Loading Dry Flowables<br>for Aerial Application                                                                                         | 0.0150                                | 350                                   | 41.2                       | 8.96                           | 0.000049                    | 0.00059                         | 0.00064                    | 1,500                       | 130               | 120                       |
| Mixer/Loader – Risk Estimates with Suggested Engineering Control (Water Soluble Packets)                                                       |                                       |                                       |                            |                                |                             |                                 |                            |                             |                   |                           |
| Mixing/Loading Dry Flowables<br>for Groundboom Application                                                                                     | 0.0150                                | 80                                    | 9.8                        | 0.24                           | 0.0000026                   | 0.0000036                       | 0.0000062                  | 28,000                      | 21,000            | 12,000                    |
| Mixing/Loading Dry Flowables<br>for Aerial Application                                                                                         | 0.0150                                | 350                                   | 9.8                        | 0.24                           | 0.000012                    | 0.000016                        | 0.000027                   | 6,500                       | 4,800             | 2,700                     |

a Application Rates based on proposed uses for emamectin benzoate (Proclaim® Insecticide, EPA Reg. No. 100-904).

b Acres Treated Per Day is taken from Exposure Science Advisory Council (ExpoSAC) Policy No. 9.1.

c UEs = Unit Exposures based on PHED Version 1.1, ORETF, or AHETF data. Baseline = no respirator.

d Dose (mg/kg/day) = daily unit exposure ( $\mu\text{g/lb ai}$ ) x application rate (lb ai/acre) x amount handled /day (acre/day) x conversion factor (1 mg/1,000  $\mu\text{g}$ ) x absorption factor (%) / body weight (80 kg).

e Total Dose = Dermal Dose (mg/kg/day) + Inhalation Dose (mg/kg/day).

f Total MOE = NOAEL / Total Dose (mg/kg/day). ST/IT Dermal/Inhalation NOAEL = 0.075 mg/kg/day. ST level of concern = 300. IT level of concern = 1000.



## 5.2 Occupational Post-Application Exposures and Risk Estimates

Agricultural workers performing typical post-application activities (e.g. scouting, irrigation, harvesting, etc.) may receive exposure to emamectin benzoate residues.

### 5.2.1 Data and Assumptions for Post-Application Dermal Exposure Scenarios

Chemical-specific dislodgeable foliar residue (DFR) studies for emamectin benzoate are not available. Therefore, this assessment uses HED's default assumption that 25% of the application is available for transfer on day 0 following the application and the residues dissipate at a rate of 10% each following day. In addition, HED has identified transfer coefficients (TCs, expressed in units  $\text{cm}^2/\text{hr}$ ) relative to the various activities which express the amount of foliar contact over time during each of the activities identified and are dependent on the task performed and the crop. TC values are taken from those appearing in Exposure SAC Policy No. 3.1, "Agriculture Transfer Coefficients." These values are based on data analyzed from other pesticides on a variety of crops. In addition to the DFR data and the maximum dermal TCs (summarized in Table 7), the following assumptions were used in the post-application assessment:

- Max Application Rate = 0.0150 lb ai/A for proposed new use on cucurbit vegetables,
- Exposure Duration = 8 hours per day,
- Body Weight = 80 kg for average adult for short-/intermediate-term durations,
- Dermal Absorption = 1.8%, and
- Fraction of ai retained on foliage is assumed to be 25% (0.25) on day zero for agricultural crops (default values established by HED ExpoSAC).
- The initial fraction of ai retained is assumed to further dissipate at the rate of 10% (0.1) per day on following days (default values established by HED ExpoSAC).

HED's post-application exposure estimates are based on surrogate data. The TCs are considered to be central tendency. Maximum application rates were used in this assessment. Overall, the post-application risk estimates are characterized as being central to high-end estimates. The post-application activity scenarios along with respective TCs are summarized in Table 7.

| Table 7. Anticipated Post-Application Activities and Dermal Transfer Coefficients. |                            |                 |                         |                                                           |
|------------------------------------------------------------------------------------|----------------------------|-----------------|-------------------------|-----------------------------------------------------------|
| Proposed Crops                                                                     | Policy Crop Group Category | Foliage Density | Transfer Coefficients   | Activities                                                |
|                                                                                    |                            |                 | $\text{cm}^2/\text{hr}$ |                                                           |
| Cucurbit Vegetables (Crop Group 9)                                                 | Vegetable, cucurbit        | full            | 1,900                   | irrigation (hand set)                                     |
|                                                                                    |                            | full            | 550                     | hand harvesting, turning, training, mechanical harvesting |
|                                                                                    |                            | full            | 230                     | transplanting                                             |
|                                                                                    |                            | min             | 90                      | scouting, hand weeding, hand pruning, thinning fruit      |
|                                                                                    |                            | full            | 90                      | scouting, hand weeding, hand pruning, thinning fruit      |

### Equations/Calculations

The following equations were used to calculate risk estimates for workers performing post-application activities:

$$DFR_t (\mu\text{g}/\text{cm}^2) = AR (\text{lb ai}/\text{acre}) \times F \times (1-D)^t \times 4.54\text{E}8 \mu\text{g}/\text{lb} \times 2.47\text{E}-8 \text{ acre}/\text{cm}^2$$

Where:

- DFR<sub>t</sub> = dislodgeable foliage residue on day "t" ( $\mu\text{g}/\text{cm}^2$ ),
- AR = application rate (lb ai/acre),
- F = fraction of ai retained on foliage (unitless), and
- D = fraction of residue that dissipates daily (unitless).

$$DD_t (\text{mg}/\text{kg}\cdot\text{day}) = \frac{DFR_t (\mu\text{g}/\text{cm}^2) \times 1\text{E}-3 \text{ mg}/\mu\text{g} \times TC (\text{cm}^2/\text{hr}) \times DA (1.8\%) \times ET (\text{hrs})}{BW (\text{kg})}$$

Where:

- DD<sub>t</sub> = daily dermal dose on day "t,"
- t = number of days after application day (days),
- DFR<sub>t</sub> = dislodgeable foliage residue on day "t" ( $\mu\text{g}/\text{cm}^2$ ),
- TC = transfer coefficient ( $\text{cm}^2/\text{hr}$ ),
- DA = dermal absorption factor (unitless),
- ET = exposure time (hr/day), and
- BW = body weight (kg).

$$\text{Margin of Exposure (MOE)} = \frac{\text{NOAEL (mg/kg/day)}}{\text{Average Daily Dose (mg/kg/day)}}$$

Where:

- MOE = Margin of exposure value used by HED to represent risk or how close a chemical exposure is to being a concern (unitless),
- ADD = Average daily dose (ADD) is absorbed dose received from exposure to pesticide, and
- NOAEL = Dose level in a toxicity study, where no observed adverse effects occurred in the study.

### **5.2.2 Post-Application Dermal Exposure and Risk Estimates**

The post-application exposure associated with agricultural crops is summarized in Table 8. For short-term exposure duration, all scenarios resulted in MOEs greater than short-term LOC of 300 (ranging from 520 to 11,000) on day 0 (12 hours after application) and, therefore, are not of concern to HED. For intermediate-term exposure durations, risk estimates are less than the intermediate-term LOC of 1000 and are of concern on day 0 (12 hours after application).



**Table 8. Short- and Intermediate-Term Post-Application Exposures and Risk Estimates for Emamectin Benzoate for Cucurbit Vegetables (Crop Group 9).**

| Activity                                                  | Transfer Coefficient | Days After Treatment | DFR <sup>a</sup>          | Daily Dermal Dose <sup>b</sup>   | Dermal MOE <sup>c</sup>       |
|-----------------------------------------------------------|----------------------|----------------------|---------------------------|----------------------------------|-------------------------------|
|                                                           |                      |                      | $\mu\text{g}/\text{cm}^2$ | $\text{mg}/\text{kg}/\text{day}$ | ST LOC = 300<br>IT LOC = 1000 |
| irrigation (hand set)                                     | 1,900                | 0<br>(12 hours)      | 0.0421                    | 0.000144                         | 520                           |
|                                                           |                      | 1                    | 0.0378                    | 0.000129                         | 580                           |
|                                                           |                      | 2                    | 0.0341                    | 0.000116                         | 640                           |
|                                                           |                      | 3                    | 0.0307                    | 0.000105                         | 720                           |
|                                                           |                      | 4                    | 0.0276                    | 0.000094                         | 790                           |
|                                                           |                      | 5                    | 0.0248                    | 0.000085                         | 880                           |
|                                                           |                      | 6                    | 0.0223                    | 0.000076                         | 980                           |
|                                                           |                      | 7                    | 0.0201                    | 0.000069                         | 1,100                         |
| hand harvesting, turning, training, mechanical harvesting | 550                  | 0<br>(12 hours)      | 0.0421                    | 0.000042                         | 1,800                         |
| transplanting                                             | 230                  | 0<br>(12 hours)      | 0.0421                    | 0.000017                         | 4,300                         |
| scouting, hand weeding, hand pruning, thinning fruit      | 90                   | 0<br>(12 hours)      | 0.0421                    | 0.0000068                        | 11,000                        |

a DFR ( $\mu\text{g}/\text{cm}^2$ ) = application rate (0.015 lb ai/acre) x fraction of application rate dislodgeable on day 0 (25%) x (1 - fraction of residue that dissipates daily 10%)<sup>1</sup> x 4.54E8  $\mu\text{g}/\text{lb}$  x 2.47E-8 acre/ $\text{cm}^2$ .

b Short-/Intermediate-Term Daily Dermal Dose = [DFR ( $\mu\text{g}/\text{cm}^2$ ) x Transfer Coefficient x 0.001 mg/ $\mu\text{g}$  x 8 hrs/day x dermal absorption 1.8%] + body weight (80 kg adult).

c Short-/Intermediate-Term MOE = NOAEL (mg/kg/day)/Daily Dermal Dose (mg/kg/day). ST/IT NOAEL = 0.075 mg/kg/day.

### Restricted Entry Interval

Typically, under WPS for Agricultural Pesticides, active ingredients classified as acute Toxicity Category III or IV for Acute Dermal, Eye Irritation, and Primary Skin Irritation are assigned a 12-hour REI. However, since the intermediate-term post-application risk estimates were of concern on day 0 (12 hours following application), the 12-hour REI on the proposed label is unacceptable and the REI for cucurbit vegetables must be based on a quantitative post-application assessment. For intermediate-term exposure durations, risk estimates for hand-set irrigation are not of concern on day 7. Thus, an REI of 7 days is recommended for cucurbit vegetables.

### **5.2.3 Occupational Post-Application Inhalation Exposure**

Based on the Agency's current practices, a quantitative occupational post-application inhalation exposure assessment was not performed for emamectin benzoate at this time because the chemical has low vapor pressure ( $3.0 \times 10^{-8}$  mm Hg at 21 °C) and is applied at a low rate (0.015 lb ai/A). However, there are multiple potential sources of post-application inhalation exposure to individuals performing post-application activities in previously treated fields. These potential sources include volatilization of pesticides and resuspension of dusts and/or particulates that contain pesticides. The Agency sought expert advice and input on issues related to volatilization of pesticides from its Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (SAP) in December 2009. The Agency received the SAP's final report on March 2, 2010 (<http://www.epa.gov/scipoly/SAP/meetings/2009/120109meeting.html>) and is in the process of



evaluating the SAP report as well as available post-application inhalation exposure data generated by the Agricultural Reentry Task Force. The Agency may, as appropriate, develop policies and procedures to identify the need for and, subsequently, the way to incorporate occupational post-application inhalation exposure into the Agency's risk assessments. If new policies or procedures are put into place, the Agency may revisit the need for a quantitative occupational post-application inhalation exposure assessment for emamectin benzoate.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

**MEMORANDUM**

**DATE:** December 7, 2011

**SUBJECT:** Emamectin Benzoate. Occupational Exposure Assessment for a Proposed Use on Outdoor-Grown Plants in Commercial Nursery Production.

|                      |                                       |
|----------------------|---------------------------------------|
| PC Code: 122806      | DP Barcode: 390788                    |
| Decision No.: 449308 | Registration No.: 100-RURR            |
| Petition No.: NA     | Regulatory Action: Section 3          |
| Case No.: NA         | Risk Assessment Type: Single Chemical |
| TXR No.: NA          | CAS No.: 155569-91-8                  |
| MRID No.: NA         | 40 CFR: §180.505                      |

**FROM:** Nancy J. Tsaur, Chemist  
Risk Assessment Branch 3  
Health Effects Division (7509P)

**THROUGH:** Wade Britton, Industrial Hygienist  
Alexandra LaMay, Biologist  
Exposure Science Advisory Council (ExpoSAC)  
Health Effects Division (7509P)  
and  
Barry O'Keefe, ORE Team Leader  
Risk Assessment Branch 3  
Health Effects Division (7509P)

**TO:** Venus Eagle/Thomas Harris, RM 01  
Insecticide and Rodenticide Branch  
Registration Division (7505P)

The Registration Division (RD) requested that the Health Effects Division (HED) conduct an exposure and risk assessment for newly proposed foliar use of emamectin benzoate on outdoor-grown ornamental plants in commercial nursery production. Note: This memorandum was reviewed by the Exposure Science Advisory Council (ExpoSAC) on 12/01/2011.



## 1.0 EXECUTIVE SUMMARY

Emamectin benzoate is a semi-synthetic avermectin, consisting of two active homologous compounds (a benzoate salt mixture of a minimum of 90% 4'-epi-methylamino-4'-deoxyavermectin B<sub>1a</sub> and a maximum of 10% 4'-epi-methylamino-4'-deoxyavermectin B<sub>1b</sub>). Emamectin benzoate is an insecticide/miticide developed for the control of *lepidopteran* insects.

Syngenta is proposing a new use on outdoor-grown ornamental plants in commercial nursery production, including field- and container-grown ornamentals. Enfold™ Insecticide (EPA Reg. No. 100-RURR) is a water-dispersible granule formulation (WG) containing 5.0% active ingredient (ai), emamectin benzoate, by weight.

Based on application rate and label information, exposure is expected to occur for short- and intermediate-term durations. Chronic exposure is not expected for the proposed use patterns.

### Proposed Use Profile

Enfold™ Insecticide may be applied as a foliar spray via groundboom, airblast, or aircraft (except in New York State). Chemigation is prohibited. For high pest infestations, the maximum single application rate is 4.8 oz/A (0.015 lb ai/A). Applications may be repeated at a 7- to 14- day interval to maintain control, up to a maximum seasonal application rate of 28.8 oz/A (0.090 lb ai/A/season).

### Hazard Concerns

All endpoints were selected from a 15-day oral neurotoxicity study in the mouse. Dermal and inhalation exposures were combined and then compared to the short-term oral NOAEL of 0.075 mg/kg/day. The endpoint includes moribund sacrifices, clinical signs of neurotoxicity, decreases in body weight and food consumption and histopathological lesions in the sciatic nerve (LOAEL of 0.1 mg/kg/day). The dermal absorption rate of 1.8% used in this assessment is based on a dermal absorption study in the Rhesus monkey, while no inhalation absorption rate is used because toxicity by the inhalation route is considered to be equivalent to the estimated toxicity of the oral route of exposure. The level of concern (LOC) for short-term exposure is a margin of exposure (MOE) less than 300 [uncertainty factors (UFs) include: 10X for interspecies extrapolation, 10X for intraspecies variation; and 3X modifying factor (UF<sub>M</sub>) to account for the steepness of the dose-response curve and the severity of effects at the LOAEL (death and neuropathology)]. The LOC for intermediate-term exposure is an MOE less than 1000, which includes a 10X UF<sub>M</sub> (rather than 3X) to account for the additional uncertainty of using a short-term study for an intermediate-term risk assessment. Emamectin benzoate is classified as "Not likely to be Carcinogenic to Humans" based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.

Emamectin benzoate is acutely toxic via the oral (Toxicity Category IV) and inhalation (Toxicity Category IV) routes. Via the dermal route, emamectin benzoate is Toxicity Category III. For dermal and eye irritation, it is Toxicity Category III and IV, respectively. However, emamectin benzoate is not a dermal sensitizer.



### Residential Exposure

Residential exposures are not assessed in this document because emamectin benzoate is a Restricted Use Pesticide (RUP) and limited to use by certified applicators in commercial areas. Currently, there are no registered products that would lead to residential exposure.

### Occupational Handlers

There is potential for short- and intermediate-term occupational exposure to emamectin benzoate during handling activities (e.g. mixing, loading, application). All, except two, short-term handler exposure scenarios result in MOEs greater than the LOC of 300 at baseline and are not of concern. With suggested mitigation techniques including engineering controls of water soluble packaging for mixing/loading for aerial application, and a PF10 dust-mist respirators for open cab airblast application, all MOEs are greater than the LOC and are not of concern. Handheld equipment is not of concern if gloves are required.

For intermediate-term exposure, all mixing/loading scenarios are less than the LOC of 1000, ranging from 130 to 670. With the suggested mitigation of water soluble packaging, dermal and inhalation exposures would significantly decrease, resulting in MOEs greater than the LOC, ranging from 4,200 to 21,000. However, for one scenario (applying sprays via open cab airblast), the addition of the highest level of inhalation PPE (PF10) would still result in an MOE of concern (MOE = 320). To mitigate this high exposure scenario, the best approach is to require an enclosed cab system to minimize exposure, thus prohibiting open cab airblast systems, resulting in an MOE of 26,000. Handheld equipment is not of concern if gloves are required.

### Occupational Post-Application

There is a potential for short- and intermediate-term occupational exposure during post-application activities. Based on a post-application assessment of common agricultural practices for short-term exposure durations, the post-application MOEs do not exceed HED's LOC of 300 (MOEs ranged from 570 to 11,000) on day 0 (12 hours after application). However, since the intermediate-term post-application risk estimates were of concern (MOEs < 1000) on day 0 (12 hours following application), the 12-hour REI on the proposed label is unacceptable and an REI of 6 days is recommended for ornamentals based on a quantitative post-application assessment.

### Review of Human Research

This risk assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide or other chemical. These studies, which comprise the Pesticide Handlers Exposure Database (PHED) and the Agricultural Handler Exposure Task Force (AHETF), have been determined to require a review of their ethical conduct, have received that review, and have been determined to be ethical.

### Label Recommendation

The label must indicate the required PPE for handheld applications (i.e. applications via backpack sprayers or manually pressurized handwands).



## 2.0 HAZARD CHARACTERIZATION

All endpoints were selected from a 15-day oral neurotoxicity study in the mouse. Dermal and inhalation exposures were combined and then compared to the short-term oral NOAEL of 0.075 mg/kg/day. The endpoint includes moribund sacrifices, clinical signs of neurotoxicity, decreases in body weight and food consumption and histopathological lesions in the sciatic nerve (LOAEL of 0.1 mg/kg/day). The dermal absorption rate of 1.8% used in this assessment is based on a dermal absorption study in the Rhesus monkey, while no inhalation absorption rate is used because toxicity by the inhalation route is considered to be equivalent to the estimated toxicity of the oral route of exposure. The level of concern (LOC) for short-term exposure is a margin of exposure (MOE) less than 300 [uncertainty factors (UFs) include: 10X for interspecies extrapolation, 10X for intraspecies variation; and 3X modifying factor ( $UF_M$ ) to account for the steepness of the dose-response curve and the severity of effects at the LOAEL (death and neuropathology)]. The LOC for intermediate-term exposure is an MOE less than 1000, which includes a 10X  $UF_M$  (rather than 3X) to account for the additional uncertainty of using a short-term study for an intermediate-term risk assessment. Emamectin benzoate is classified as "Not likely to be Carcinogenic to Humans" based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.

The acute toxicity for the technical emamectin benzoate formulation (EPA Reg. No. 100-1270) used in this proposed product (EPA Reg. No. 100-RURR) is summarized in Table 1. Emamectin benzoate is acutely toxic via the oral (Toxicity Category IV) and inhalation (Toxicity Category IV) routes. Via the dermal route, emamectin benzoate is Toxicity Category III. For eye and dermal irritation, it is Toxicity Category III and IV, respectively. However, emamectin benzoate is not a dermal sensitizer.

| Table 1. Acute Toxicity Profile – Emamectin Benzoate Technical II (EPA Reg. No. 100-1270). |                                   |          |                                               |                   |
|--------------------------------------------------------------------------------------------|-----------------------------------|----------|-----------------------------------------------|-------------------|
| Guideline No.                                                                              | Study Type                        | MRID     | Results                                       | Toxicity Category |
| 870.1100                                                                                   | Acute oral - Rats                 | 47002104 | LD <sub>50</sub> for L-656,748-038 = 53 mg/kg | II                |
| 870.1200                                                                                   | Acute dermal - Rabbits (EC)       | 47002106 | LD <sub>50</sub> > 2.0 g/kg                   | III               |
| 870.1300                                                                                   | Acute inhalation - Rats           | 47002107 | LC <sub>50</sub> 0.10 mg/L                    | II                |
| 870.2400                                                                                   | Acute eye irritation - Rabbits    | 47002108 | Severe irritation                             | III               |
| 870.2500                                                                                   | Acute dermal irritation - Rabbits | 47002109 | No dermal irritation                          | IV                |
| 870.2600                                                                                   | Skin sensitization - Guinea pigs  | 47002110 | Not a dermal sensitizer                       | Negative          |

Table 2 summarizes the selected endpoints for occupational risk assessment.



**Table 2. Summary of Toxicological Doses and Endpoints for Emamectin Benzoate for Use in Occupational Human Health Risk Assessments.**

| Exposure/<br>Scenario                     | Point of<br>Departure                                                                                                                                         | Uncertainty<br>Factors                                                  | Level of Concern<br>for Risk<br>Assessment | Study and Toxicological Effects                                                                                                                                                                               |
|-------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|--------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Dermal Short-Term (1-30 days)             | NOAEL = 0.075 mg/kg/day (dermal absorption rate = 1.8%)                                                                                                       | UF <sub>A</sub> = 10X<br>UF <sub>H</sub> = 10X<br>UF <sub>M</sub> = 3X  | Occupational LOC<br>MOE = 300              | <b>15-day mouse</b><br>LOAEL = 0.1 mg/kg/day based on moribund sacrifices, clinical signs of neurotoxicity, decreases in body weight and food consumption and histopathological lesions in the sciatic nerve. |
| Dermal Intermediate-Term (1-6 months)     | NOAEL = 0.075 mg/kg/day (dermal absorption rate = 1.8%)                                                                                                       | UF <sub>A</sub> = 10X<br>UF <sub>H</sub> = 10X<br>UF <sub>M</sub> = 10X | Occupational LOC<br>MOE = 1000             | <b>15-day mouse</b><br>LOAEL = 0.1 mg/kg/day based on moribund sacrifices, clinical signs of neurotoxicity, decreases in body weight and food consumption and histopathological lesions in the sciatic nerve. |
| Inhalation Short-Term (1-30 days)         | NOAEL = 0.075 mg/kg/day (assumed equivalent to oral absorption)                                                                                               | UF <sub>A</sub> = 10X<br>UF <sub>H</sub> = 10X<br>UF <sub>M</sub> = 3X  | Occupational LOC<br>MOE = 300              | <b>15-day mouse</b><br>LOAEL = 0.1 mg/kg/day based on moribund sacrifices, clinical signs of neurotoxicity, decreases in body weight and food consumption and histopathological lesions in the sciatic nerve. |
| Inhalation Intermediate-Term (1-6 months) | NOAEL = 0.075 mg/kg/day (assumed equivalent to oral absorption)                                                                                               | UF <sub>A</sub> = 10X<br>UF <sub>H</sub> = 10X<br>UF <sub>M</sub> = 10X | Occupational LOC<br>MOE = 1000             | <b>15-day mouse</b><br>LOAEL = 0.1 mg/kg/day based on moribund sacrifices, clinical signs of neurotoxicity, decreases in body weight and food consumption and histopathological lesions in the sciatic nerve. |
| Cancer (oral, dermal, inhalation)         | Classification: "Not likely to be Carcinogenic to Humans" based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies. |                                                                         |                                            |                                                                                                                                                                                                               |

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk estimate associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies). UF<sub>M</sub> = Modifying factor to account for the steepness of the dose-response curve, severity of effects at the LOAEL (death and neuropathology), and the use of a short-term study for intermediate-term risk assessment. MOE = margin of exposure. LOC = level of concern. Dermal absorption of 1.8% is assumed.

### 3.0 PROPOSED USE PATTERNS

Endfold™ Insecticide controls the larval stages (worms/caterpillars) of several lepidopteran species and suppresses Liriomyza leafminer, Tetranychid mites, and pear psylla. It is a selective insecticide for use on herbaceous and woody ornamental plants grown outdoors (in containers or in the ground) in commercial nursery production. Woody ornamentals include (but are not



limited to) shrubs, non-bearing fruit and nut trees, Christmas trees, forest seedlings, and shade trees.

Enfold™ Insecticide may be applied as a foliar spray via groundboom, airblast, or aircraft (except in New York State). Chemigation is prohibited. For high pest infestations, the maximum single application rate is 4.8 oz/A (0.015 lb ai/A). Applications may be repeated at a 7- to 14- day interval to maintain control, up to a maximum seasonal application rate of 28.8 oz/A (0.090 lb ai/A/season). The proposed label is summarized in Table 3.

| Table 3. Use Profile for Proposed Emamectin Benzoate Uses.                                                      |                              |                                 |               |
|-----------------------------------------------------------------------------------------------------------------|------------------------------|---------------------------------|---------------|
| <i>Enfold™ Insecticide</i><br>EPA Reg. No. 100-RURR<br><i>water dispersible granule (WG), 5.0% ai by weight</i> |                              |                                 |               |
| Use Site                                                                                                        | Application Equipment        | Single Maximum Application Rate |               |
|                                                                                                                 |                              | oz/A                            | lb ai/A       |
| Outdoor Ornamentals (Ground or Container)                                                                       | Groundboom, Airblast, Aerial | 2.4-4.8                         | 0.00075-0.015 |

#### 4.0 RESIDENTIAL (NON-OCCUPATIONAL) EXPOSURE

Residential exposures are not assessed in this document because emamectin benzoate is a Restricted Use Pesticide (RUP) and limited to use by certified applicators in commercial areas. The use of emamectin benzoate on commercially grown outdoor ornamentals does not involve applications by homeowners or commercial applicators in residential settings. Currently, there are no registered products that would lead to residential exposure.

Post-application exposure to homeowners and children is possible (e.g. purchasing an ornamental treated with emamectin from a retail store) but highly unlikely. Based on HED ExpoSAC's guidance (see ExpoSAC minutes from 8/19/99 and 10/11/01), post-application exposures are not likely to occur from ornamental applications therefore, adult homeowner and children's post-application exposures were not assessed.

##### Residential Bystander Post-Application Inhalation Exposure

Based on the Agency's current practices, a quantitative post-application inhalation exposure assessment was not performed for emamectin benzoate at this time because the chemical has low vapor pressure ( $3.0 \times 10^{-8}$  mm Hg at 21 °C) and is applied at a low rate (0.015 lb ai/A).

However, volatilization of pesticides may be a potential source of post-application inhalation exposure to individuals nearby to pesticide applications. The Agency sought expert advice and input on issues related to volatilization of pesticides from its Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (SAP) in December 2009. The Agency received the SAP's final report on March 2, 2010

(<http://www.epa.gov/scipoly/SAP/meetings/2009/120109meeting.html>) and is in the process of evaluating the SAP report. The Agency may, as appropriate, develop policies and procedures to

identify the need for and, subsequently, the way to incorporate post-application inhalation exposure into the Agency's risk assessments. If new policies or procedures are put into place, the Agency may revisit the need for a quantitative post-application inhalation exposure assessment for emamectin benzoate.

#### Spray Drift

Spray drift is always a potential source of exposure to residents nearby to spraying operations. This is particularly the case with aerial application, but, to a lesser extent, could also be a potential source of exposure from the ground application method employed for the previously-registered uses of emamectin benzoate. The Agency has been working with the Spray Drift Task Force, EPA Regional Offices, and State Lead Agencies for pesticide regulation and other parties to develop the best spray drift management practices. The Agency is now requiring interim mitigation measures for aerial applications that must be placed on product labels/labeling. The Agency has completed its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, and is developing a policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air, orchard airblast, and ground hydraulic methods. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift and risk estimates associated with aerial as well as other application types where appropriate.

### **5.0 OCCUPATIONAL EXPOSURE/RISK ESTIMATES PATHWAY**

Occupational handler exposure to emamectin benzoate is expected for individuals involved in foliar applications to outdoor ornamentals (mixing, loading, and applying).

Additionally, agricultural workers performing typical post-application activities such as scouting, irrigation, and harvesting are likely to receive exposure to emamectin benzoate residues based on the repeated use pattern to maintain control of pests.

#### **5.1 Occupational Handler**

Enfold™ Insecticide may be applied as a foliar spray via groundboom, airblast, or aircraft (except in New York State). The proposed use pattern is summarized in Table 2. Handler exposure is expected to be short- or intermediate-term based on information provided on the proposed label. Table 4 summarizes the proper personal protective equipment (PPE) required on the proposed label.

| <b>Table 4. Required PPE on Label (EPA Reg. No. 100-RURR).</b> |                                                                                                                                                                               |
|----------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Ground Application (except airblast sprayers)</b>           |                                                                                                                                                                               |
| Applicators, Mixers, Loaders,<br>Other Handlers                | Long-sleeved shirt and long pants<br>Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber<br>Shoes plus socks |



| <b>Table 4. Required PPE on Label (EPA Reg. No. 100-RURR).</b>                                                                                                         |                                                                                                                                                                                                                                                                                              |                                                                                                                                                                               |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Airblast Application</b>                                                                                                                                            |                                                                                                                                                                                                                                                                                              |                                                                                                                                                                               |
| Mixers, Loaders, Other Handlers                                                                                                                                        | Long-sleeved shirt and long pants<br>Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber<br>Shoes plus socks                                                                                                                |                                                                                                                                                                               |
| Applicators using OPEN CAB                                                                                                                                             | Long-sleeved shirt and long pants<br>Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber<br>Shoes plus socks                                                                                                                |                                                                                                                                                                               |
| Applicators using ENCLOSED CAB<br>NOTE: Once inside the cab, applicator must remove gloves and store them in a chemical-resistant container such as a plastic bag.     | While inside the cab must wear:<br>Long-sleeved shirt and long pants<br>Shoes plus socks                                                                                                                                                                                                     | When entering or leaving the cab must also wear:<br>Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber.     |
| <b>Aerial Application</b>                                                                                                                                              |                                                                                                                                                                                                                                                                                              |                                                                                                                                                                               |
| Mixers, Loaders, Other Handlers                                                                                                                                        | Coveralls over long-sleeved shirt and long pants<br>Shoes plus socks<br>Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber<br>Dust/Mist-filtering respirator or a NIOSH-approved respirator with any N, R, P, or HE filter |                                                                                                                                                                               |
| Applicators (ENCLOSED Cockpit)<br>NOTE: Once inside the cockpit, applicator must remove gloves and store them in a chemical-resistant container such as a plastic bag. | While inside the cockpit must wear:<br>Long-sleeved shirt and long pants<br>Shoes plus socks                                                                                                                                                                                                 | When entering or leaving the cockpit must also wear:<br>Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber. |
| Flaggers                                                                                                                                                               | Long-sleeved shirt and long pants<br>Shoes plus socks<br>Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber.                                                                                                               |                                                                                                                                                                               |

The quantitative exposure/risk assessment developed for occupational handlers is based on the following exposure scenarios:

#### Mixer/Loaders

1. Mixing/loading dry flowables to support groundboom applications,
2. Mixing/loading dry flowables to support airblast applications,
3. Mixing/loading dry flowables to support aerial applications,

#### Flaggers

4. Flagging to support aerial application,



#### Applicators

5. Applying sprays with groundboom equipment,
6. Applying sprays with airblast equipment, and
7. Applying sprays with aerial equipment,

#### Mixer/Loader/Applicators

8. Mixing/loading/applying sprays with backpack sprayer, and
9. Mixing/loading/applying sprays with low pressure handwand.

### **5.1.1 Data and Assumptions for Handler Exposure Scenarios**

#### Unit Exposures

No chemical-specific handler exposure data were submitted in support of this proposed use of emamectin benzoate on outdoor ornamentals. To assess handler exposures for regulatory actions when chemical-specific monitoring data are not available, HED relies on the most scientifically-reliable surrogate data currently available from various sources such as PHED, AHETF, and the Outdoor Residential Exposure Task Force (ORETF). Some of these data, such as the industry task force data, are compensatory, subject to the data protection provisions of FIFRA. HED policy on use of surrogate data is described in more detail on the Agency's website (<http://www.epa.gov/pesticides/science/handler-exposure-data.html>). Scenario-specific surrogate exposure data, including their sources, are presented in the "Occupational Pesticide Handler Unit Exposure Surrogate Reference Table" (<http://www.epa.gov/pesticides/science/handler-exposure-table.pdf>).

#### Area/Amount Treated

Based on HED ExpoSAC Policy No. 9.1, the area treated in a day was assumed to be:

- 80 acres for mixing/loading to support groundboom applications,
- 40 acres for mixing/loading to support airblast applications,
- 200 acres for mixing/loading to support aerial applications,
- 350 acres for flagging to support aerial treatment,
- 80 acres for applying with groundboom equipment,
- 40 acres for applying with airblast equipment, and
- 200 acres for applying with aerial equipment, and
- 40 gallons for mixing/loading/applying with handheld equipment (i.e. backpack sprayer and manually pressurized handwand).

#### Application Rate

For high pest infestations, the maximum single application rate is 4.8 oz/A (0.015 lb ai/A). Applications may be repeated at a 7- to 14- day interval to maintain control, up to a maximum seasonal application rate of 28.8 oz/A (0.090 lb ai/A/season). For handheld equipment, the label indicates that the most concentrated application volume is 50 gal/A, which equates to a single maximum application rate of 0.003 lb ai/gal.

#### Body Weight

The average adult body weight of 70 kg was used for estimating short- and intermediate-term dermal and inhalation dose because the selected toxicological PoDs are not based on developmental effects.

#### Absorption Factors

- Since the short- and intermediate-term dermal endpoints are based on an oral study, a dermal absorption factor of 1.8% is used to estimate dermal exposure for both durations.
- Since the short- and intermediate-term inhalation endpoint was based on an oral study and no inhalation absorption data are available, toxicity by the inhalation route is considered to be equivalent to the estimated toxicity by the oral route of exposure.

#### Equations and Calculations

##### ***Daily Dose***

Daily dose (dermal and inhalation) is calculated by normalizing the daily exposure (dermal or inhalation) value by body weight and accounting for absorption factors.

$$\text{Average Daily Dose (mg/kg/day)} = \text{Daily Exposure (mg ai/day)} \times \frac{\{\text{Absorption Factor (\%/100)}\}}{\text{Body Weight (kg)}}$$

Where:

- Average Daily Dose = Absorbed dose received from exposure to a pesticide in a given scenario (mg pesticide active ingredient/kg body weight/day),
- Daily Exposure = Amount (mg ai/day) deposited on the surface of the skin that is available for dermal absorption or amount inhaled that is available for inhalation absorption,
- Absorption Factor = A measure of the amount of chemical that crosses a biological boundary such as the skin or lungs, and
- Body Weight = Body weight determined to represent the population of interest in a risk assessment.

##### ***Margin of Exposure (MOE)***

The daily inhalation dose received by occupational handlers was compared to the appropriate PoD (i.e. NOAELs) to assess the risk to occupational handlers. All MOE values were calculated using the following formula:

$$\text{MOE} = \frac{\text{NOAEL (mg/kg/day)}}{\text{Average Daily Dose (mg/kg/day)}}$$

Where:

- MOE = Margin of exposure value used by HED to represent risk or how close a chemical exposure is to being a concern (unitless),
- ADD = Average daily dose (ADD) is absorbed dose received from exposure to pesticide, and
- NOAEL = Dose level in a toxicity study, where no observed adverse effects occurred in the study.

#### ***Combined Risk Estimates***



Dermal and inhalation risk estimates were combined in this assessment, since the toxicological effects for the dermal and inhalation routes were the same. Since short- and intermediate-term dermal and inhalation PoDs were the same, risk estimates were combined using the following formula:

$$\text{Total MOE} = \text{NOAEL}/(\text{Dermal Dose} + \text{Inhalation Dose})$$

### **5.1.2 Handler Exposure and Risk Estimates**

Summaries of the short- and intermediate-term risk estimates for occupational handlers are included in Tables 5 through 8. The maximum application rate for each exposure scenario is presented as the worst case scenario.

#### Short-Term Exposure Duration

At baseline, without any required PPE, all handler scenarios (mixer/loader, applicator, and flagger) resulted in short-term combined (dermal + inhalation) MOEs greater than the short-term LOC of 300, except for:

1. mixing/loading dry flowables for aerial application (MOE = 130) and
2. applying sprays via open cab airblast (MOE = 240).

At the required levels of PPE as summarized in Table 4 (namely, double layer clothing and chemical-resistant gloves), both scenarios remain of concern (see Table 6).

Mitigation via water-soluble packets (WSPs) would significantly decrease both dermal and inhalation exposure during mixing/loading activities for aerial applications, resulting in an MOE of 4,200 (see Table 8).

Possible options for mitigation for open cab airblast systems include a PF10 dust-mist respirator. With the suggested additional inhalation PPE, the risk estimates for applying sprays via open cab airblast result in an MOE of 320 (see Table 7), which is greater than the LOC of 300.

Table 9 summarizes the risk estimates for handheld equipment (backpack sprayer and manually pressurized handwand). At baseline, the backpack sprayer does not result in a risk estimate of concern (MOE = 1,200). However, the manually pressurized handwand requires gloves in order to result in a risk estimate that is not of concern (MOE = 12,000). NOTE: The label must indicate all required PPE for handheld equipment.

#### Intermediate-Term Exposure Duration

At baseline, four scenarios exceed the intermediate-term LOC of 1000:

1. mixing/loading dry flowables for groundboom (MOE = 340),
2. mixing/loading dry flowables for airblast application (MOE = 670),
3. mixing/loading dry flowables for aerial application (MOE = 130), and
4. applying sprays via open cab airblast (MOE = 240).

At the required levels of PPE as summarized in Table 4 (namely, double layer clothing and chemical-resistant gloves), all four scenarios still result in combined MOEs less than the LOC (see Table 6).



Mitigation via water-soluble packets (WSPs) would significantly decrease both dermal and inhalation exposure during mixing/loading activities for ground, airblast, and aerial applications, resulting in MOEs of 11,000, 21,000, and 4,200, respectively. Table 8 shows the risk estimates for occupational handlers with added engineering controls of WSPs.

Possible options for mitigation for open cab airblast systems include a PF10 dust-mist respirator. With the suggested additional inhalation PPE, the risk estimates for applying sprays via open cab airblast result in an MOE of 320 (see Table 7), which is still less than the LOC of 1000 and of concern. With specific regard to the open cab airblast scenario, the best mitigation approach is to require an airblast system with an enclosed cab to protect the handler from excess exposure to emamectin benzoate, thus prohibiting the use of open cab airblast systems. The baseline MOE for enclosed cab airblast application is 26,000 (see Table 5).

Table 9 summarizes the risk estimates for handheld equipment (backpack sprayer and manually pressurized handwand). The results are identical to those of the short-term duration of exposure: at baseline, the backpack sprayer does not result in a risk estimate of concern (MOE = 1,200). However, the manually pressurized handwand requires gloves in order to result in a risk estimate that is not of concern (MOE = 12,000). NOTE: The label must indicate all required PPE for handheld equipment.

| Exposure Scenario                                       | Application Rate <sup>a</sup> | Area Treated Daily <sup>b</sup> | Baseline Dermal Unit Exposures <sup>c</sup> | Baseline Inhalation Unit Exposures <sup>c</sup> | Baseline Dermal Dose <sup>d</sup> | Baseline Inhalation Dose <sup>d</sup> | Total Dose <sup>e</sup>       | Baseline Total MOE <sup>f</sup> |
|---------------------------------------------------------|-------------------------------|---------------------------------|---------------------------------------------|-------------------------------------------------|-----------------------------------|---------------------------------------|-------------------------------|---------------------------------|
|                                                         | lb ai/A                       | acres                           | µg/lb ai                                    | µg/lb ai                                        | mg/kg/day                         | mg/kg/day                             | ST LOC = 300<br>IT LOC = 1000 | ST LOC = 300<br>IT LOC = 1000   |
| <b>Mixer/Loader</b>                                     |                               |                                 |                                             |                                                 |                                   |                                       |                               |                                 |
| Mixing/Loading Dry Flowables for Groundboom Application | 0.015                         | 80                              | 227                                         | 8.96                                            | 0.000070                          | 0.00015                               | 0.00022                       | 340                             |
| Mixing/Loading Dry Flowables for Airblast Application   | 0.015                         | 40                              | 227                                         | 8.96                                            | 0.000035                          | 0.000077                              | 0.00011                       | 670                             |
| Mixing/Loading Dry Flowables for Aerial Application     | 0.015                         | 200                             | 227                                         | 8.96                                            | 0.00018                           | 0.00038                               | 0.00056                       | 130                             |
| <b>Flagger</b>                                          |                               |                                 |                                             |                                                 |                                   |                                       |                               |                                 |
| Flagging for Aerial Application                         | 0.015                         | 350                             | 11                                          | 0.35                                            | 0.000015                          | 0.000026                              | 0.000041                      | 1,800                           |
| <b>Applicator</b>                                       |                               |                                 |                                             |                                                 |                                   |                                       |                               |                                 |
| Applying Sprays via Groundboom Equipment                | 0.015                         | 80                              | 78.6                                        | 0.34                                            | 0.000024                          | 0.0000058                             | 0.000030                      | 2,500                           |
| Applying Sprays via Airblast Equipment (Open Cab)       | 0.015                         | 40                              | 1770                                        | 4.71                                            | 0.00027                           | 0.000040                              | 0.00031                       | 240                             |
| Applying Sprays via Airblast Equipment (Enclosed Cab)   | 0.015                         | 40                              | 14.6                                        | 0.068                                           | 0.0000023                         | 0.00000058                            | 0.0000028                     | 26,000                          |
| Applying Sprays via Aerial Equipment                    | 0.015                         | 200                             | 5                                           | 0.068                                           | 0.0000039                         | 0.0000029                             | 0.0000068                     | 11,000                          |

a Application Rates based on proposed uses for emamectin benzoate (Enfold™ Fungicide, EPA Reg. No. 100-RURR).

b Acres Treated Per Day is taken from Exposure Science Advisory Council (ExpoSAC) Policy No. 9.1.

c Unit Exposures based on PHED Version 1.1, ORETF, or AHETF data. Baseline = no gloves, no respirator.

d Dose (mg/kg/day) = daily unit exposure (µg/lb ai) x application rate (lb ai/acre) x amount handled /day (acres/day) x conversion factor (1 mg/1,000 µg) x absorption factor (%) / body weight (70 kg).

e Total Dose = Dermal Dose (mg/kg/day) + Inhalation Dose (mg/kg/day).

f Total MOE = NOAEL / Total Dose (mg/kg/day). ST/IT Dermal/Inhalation NOAEL = 0.075 mg/kg/day. ST level of concern = 300. IT level of concern = 1000.



**Table 6. Emeactin Benzoate Short- and Intermediate Term Occupational Exposures and Risk Estimates for Outdoor Ornamental Use with Required Dermal PPE (Listed on Proposed Label).**

| Exposure Scenario                                       | Application Rate <sup>a</sup> | Area Treated Daily <sup>b</sup> | Double Layer + Gloves Dermal Unit Exposures <sup>c</sup> | Baseline Inhalation Unit Exposures <sup>c</sup> | Double Layer + Gloves Dermal Dose <sup>d</sup> | Baseline Inhalation Dose <sup>d</sup> | Total Dose <sup>e</sup>       | Double Layer + Gloves, No Respirator Total MOE <sup>f</sup> |
|---------------------------------------------------------|-------------------------------|---------------------------------|----------------------------------------------------------|-------------------------------------------------|------------------------------------------------|---------------------------------------|-------------------------------|-------------------------------------------------------------|
|                                                         | lb ai/A                       | acres                           | µg/lb ai                                                 | µg/lb ai                                        | mg/kg/day                                      | mg/kg/day                             | ST LOC = 300<br>IT LOC = 1000 | ST LOC = 300<br>IT LOC = 1000                               |
| <b>Mixer/Loader</b>                                     |                               |                                 |                                                          |                                                 |                                                |                                       |                               |                                                             |
| Mixing/Loading Dry Flowables for Groundboom Application | 0.015                         | 80                              | 41.2                                                     | 8.96                                            | 0.000013                                       | 0.00015                               | 0.00017                       | <b>450</b>                                                  |
| Mixing/Loading Dry Flowables for Airblast Application   | 0.015                         | 40                              | 41.2                                                     | 8.96                                            | 0.0000064                                      | 0.000077                              | 0.000083                      | <b>900</b>                                                  |
| Mixing/Loading Dry Flowables for Aerial Application     | 0.015                         | 200                             | 41.2                                                     | 8.96                                            | 0.000031                                       | 0.00038                               | 0.00042                       | <b>180</b>                                                  |
| <b>Flagger</b>                                          |                               |                                 |                                                          |                                                 |                                                |                                       |                               |                                                             |
| Flagging for Aerial Application                         | 0.015                         | 350                             | 10.6                                                     | 0.35                                            | 0.000014                                       | 0.000026                              | 0.000041                      | 1,800                                                       |
| <b>Applicator</b>                                       |                               |                                 |                                                          |                                                 |                                                |                                       |                               |                                                             |
| Applying Sprays via Groundboom Equipment                | 0.015                         | 80                              | 12.6                                                     | 0.34                                            | 0.0000039                                      | 0.0000058                             | 0.0000097                     | 7,700                                                       |
| Applying Sprays via Airblast Equipment (Open Cab)       | 0.015                         | 40                              | 1480                                                     | 4.71                                            | 0.00023                                        | 0.000040                              | 0.00027                       | <b>280</b>                                                  |

a Application Rates based on proposed uses for emeactin benzoate (Enfold™ Fungicide, EPA Reg. No. 100-RURR).

b Acres Treated Per Day is taken from Exposure Science Advisory Council (ExpoSAC) Policy No. 9.1.

c Unit Exposures based on PHED Version 1.1, ORETF, or AHETF data. Baseline = no respirator.

d Dose (mg/kg/day) = daily unit exposure (µg/lb ai) x application rate (lb ai/acre) x amount handled /day (acres/day) x conversion factor (1 mg/1,000 µg) x absorption factor (%) / body weight (70 kg).

e Total Dose = Dermal Dose (mg/kg/day) + Inhalation Dose (mg/kg/day).

f Total MOE = NOAEL / Total Dose (mg/kg/day). ST/IT Dermal/Inhalation NOAEL = 0.075 mg/kg/day. ST level of concern = 300. IT level of concern = 1000.



| Table 7. Emamectin Benzoate Short- and Intermediate Term Occupational Exposures and Risk Estimates for Outdoor Ornamental Use with Required Dermal PPE (Listed on Proposed Label) and Suggested Inhalation PPE (PF10). |                               |                                 |                                                          |                                             |                                                |                                   |                               |                                                    |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|---------------------------------|----------------------------------------------------------|---------------------------------------------|------------------------------------------------|-----------------------------------|-------------------------------|----------------------------------------------------|
| Exposure Scenario                                                                                                                                                                                                      | Application Rate <sup>a</sup> | Area Treated Daily <sup>b</sup> | Double Layer + Gloves Dermal Unit Exposures <sup>c</sup> | PF10 Inhalation Unit Exposures <sup>c</sup> | Double Layer + Gloves Dermal Dose <sup>d</sup> | PF10 Inhalation Dose <sup>d</sup> | Total Dose <sup>e</sup>       | Double Layer + Gloves, PF10 Total MOE <sup>f</sup> |
|                                                                                                                                                                                                                        | lb ai/A                       | acres                           | µg/lb ai                                                 | µg/lb ai                                    | mg/kg/day                                      | mg/kg/day                         | ST LOC = 300<br>IT LOC = 1000 | ST LOC = 300<br>IT LOC = 1000                      |
| Applying Sprays via Airblast Equipment (Open Cab)                                                                                                                                                                      | 0.015                         | 40                              | 1480                                                     | 0.471                                       | 0.00023                                        | 0.0000040                         | 0.00023                       | 320                                                |

| Table 8. Emamectin Benzoate Short- and Intermediate Term Occupational Exposures and Risk Estimates for Outdoor Ornamental Use with Suggested Engineering Control (Water Soluble Packets). |                               |                                 |                                        |                                                 |                              |                                       |                               |                                            |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|---------------------------------|----------------------------------------|-------------------------------------------------|------------------------------|---------------------------------------|-------------------------------|--------------------------------------------|
| Exposure Scenario                                                                                                                                                                         | Application Rate <sup>a</sup> | Area Treated Daily <sup>b</sup> | WSP Dermal Unit Exposures <sup>c</sup> | Baseline Inhalation Unit Exposures <sup>c</sup> | WSP Dermal Dose <sup>d</sup> | Baseline Inhalation Dose <sup>d</sup> | Total Dose <sup>e</sup>       | WSP + No Respirator Total MOE <sup>f</sup> |
|                                                                                                                                                                                           | lb ai/A                       | acres                           | µg/lb ai                               | µg/lb ai                                        | mg/kg/day                    | mg/kg/day                             | ST LOC = 300<br>IT LOC = 1000 | ST LOC = 300<br>IT LOC = 1000              |
| <b>Mixer/Loader</b>                                                                                                                                                                       |                               |                                 |                                        |                                                 |                              |                                       |                               |                                            |
| Mixing/Loading Dry Flowables for Groundboom Application                                                                                                                                   | 0.015                         | 80                              | 9.8                                    | 0.24                                            | 0.0000030                    | 0.0000041                             | 0.0000071                     | 11,000                                     |
| Mixing/Loading Dry Flowables for Airblast Application                                                                                                                                     | 0.015                         | 40                              | 9.8                                    | 0.24                                            | 0.0000015                    | 0.0000021                             | 0.0000036                     | 21,000                                     |
| Mixing/Loading Dry Flowables for Aerial Application                                                                                                                                       | 0.015                         | 200                             | 9.8                                    | 0.24                                            | 0.0000076                    | 0.000010                              | 0.000018                      | 4,200                                      |

a Application Rates based on proposed uses for emamectin benzoate (Enfold™ Fungicide, EPA Reg. No. 100-RURR).

b Acres Treated Per Day is taken from Exposure Science Advisory Council (ExpoSAC) Policy No. 9.1.

c Unit Exposures based on PHED Version 1.1, ORETF, or AHETF data. Baseline = no respirator.

d Dose (mg/kg/day) = daily unit exposure (µg/lb ai) x application rate (lb ai/acre) x amount handled /day (acres/day) x conversion factor (1 mg/1,000 µg) x absorption factor (%) / body weight (70 kg).

e Total Dose = Dermal Dose (mg/kg/day) + Inhalation Dose (mg/kg/day).

f Total MOE = NOAEL / Total Dose (mg/kg/day). ST/IT Dermal/Inhalation NOAEL = 0.075 mg/kg/day. ST level of concern = 300. IT level of concern = 1000.

**Table 9. Enamectin Benzoate Short- and Intermediate Term Occupational Exposures and Risk Estimates for Outdoor Ornamental Use with Handheld Equipment.**

| Exposure Scenario                                                    | Application Rate <sup>a</sup> | Amount Handled Daily <sup>b</sup> | Dermal Unit Exposures <sup>c</sup> | Inhalation Unit Exposures <sup>c</sup> | Dermal Dose <sup>d</sup> | Inhalation Dose <sup>d</sup> | Total Dose <sup>e</sup>                     | Total MOE <sup>f</sup>                      |
|----------------------------------------------------------------------|-------------------------------|-----------------------------------|------------------------------------|----------------------------------------|--------------------------|------------------------------|---------------------------------------------|---------------------------------------------|
|                                                                      | <i>lb ai/gal</i>              | <i>gallons</i>                    | <i>µg/lb ai</i>                    | <i>µg/lb ai</i>                        | <i>mg/kg/day</i>         | <i>mg/kg/day</i>             | <i>ST LOC = 300</i><br><i>IT LOC = 1000</i> | <i>ST LOC = 300</i><br><i>IT LOC = 1000</i> |
| <b>Mixer/Loader/Applicator BASELINE</b>                              |                               |                                   |                                    |                                        |                          |                              |                                             |                                             |
| Backpack Sprayer                                                     | 0.0003                        | 40                                | 13200                              | 140                                    | 0.000041                 | 0.000024                     | 0.000065                                    | 1,200                                       |
| Manually Pressurized Handwand                                        | 0.0003                        | 40                                | 100000                             | 30                                     | 0.00031                  | 0.0000051                    | 0.00031                                     | <b>240</b>                                  |
| <b>Mixer/Loader/Applicator SINGLE LAYER + GLOVES (no respirator)</b> |                               |                                   |                                    |                                        |                          |                              |                                             |                                             |
| Backpack Sprayer                                                     | 0.0003                        | 40                                | 11200                              | 140                                    | 0.000035                 | 0.000024                     | 0.000059                                    | 1,300                                       |
| Manually Pressurized Handwand                                        | 0.0003                        | 40                                | 430                                | 30                                     | 0.0000013                | 0.0000051                    | 0.0000065                                   | 12,000                                      |

a Application Rates based on proposed uses for emamectin benzoate (Enfold™ Fungicide, EPA Reg. No. 100-RURR).

b Gallons Handled Per Day is taken from Exposure Science Advisory Council (ExpoSAC) Policy No. 9.1.

c Unit Exposures based on PHED Version 1.1 (handwand) or AHETF data (backpack). Baseline = no respirator.

d Dose (mg/kg/day) = daily unit exposure (µg/lb ai) x application rate (lb ai/gal) x amount handled /day (gal/day) x conversion factor (1 mg/1,000 µg) x absorption factor (%) / body weight (70 kg).

e Total Dose = Dermal Dose (mg/kg/day) + Inhalation Dose (mg/kg/day).

f Total MOE = NOAEL / Total Dose (mg/kg/day). ST/IT Dermal/Inhalation NOAEL = 0.075 mg/kg/day. ST level of concern = 300. IT level of concern = 1000.



## 5.2 Occupational Post-Application Exposures and Risk Estimates

Agricultural workers performing typical post-application activities (e.g. scouting, irrigation, harvesting, etc.) may receive exposure to emamectin benzoate residues.

### 5.2.1 Data and Assumptions for Post-Application Dermal Exposure Scenarios

Chemical-specific dislodgeable foliar residue (DFR) studies for emamectin benzoate are not available. Therefore, this assessment uses HED's default assumption that 20% of the application is available for transfer on day 0 following the application and the residues dissipate at a rate of 10% each following day. In addition, HED has identified transfer coefficients (TCs, expressed in units  $\text{cm}^2/\text{hr}$ ) relative to the various activities which express the amount of foliar contact over time during each of the activities identified and are dependent on the task performed and the crop. TC values are taken from those appearing in Exposure SAC Policy No. 3.1, "Agriculture Transfer Coefficients." These values are based on data analyzed from other pesticides on a variety of crops. In addition to the DFR data and the maximum dermal TCs (summarized in Table 9), the following assumptions were used in the post-application assessment:

- Max Application Rate = 0.0150 lb ai/A for proposed new use on outdoor ornamentals,
- Exposure Duration = 8 hours per day,
- Body Weight = 70 kg for average adult for short-/intermediate-term durations,
- Dermal Absorption = 1.8%, and
- Fraction of ai retained on foliage is assumed to be 20% (0.2) on day zero for agricultural crops (default values established by HED ExpoSAC).
- The initial fraction of ai retained is assumed to further dissipate at the rate of 10% (0.1) per day on following days (default values established by HED ExpoSAC).

HED's post-application exposure estimates are based on surrogate data. The TCs are considered to be central tendency. Maximum application rates were used in this assessment. Overall, the post-application risk estimates are characterized as being central to high-end estimates. The post-application activity scenarios along with respective TCs are summarized in Table 10.

| Table 10. Anticipated Post-Application Activities and Dermal Transfer Coefficients. |                            |                 |                         |                                                                                                                                         |
|-------------------------------------------------------------------------------------|----------------------------|-----------------|-------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|
| Proposed Crops                                                                      | Policy Crop Group Category | Foliage Density | Transfer Coefficients   | Activities                                                                                                                              |
|                                                                                     |                            |                 | $\text{cm}^2/\text{hr}$ |                                                                                                                                         |
| Commercially Grown Outdoor Ornamentals (Field- or Container-Grown)                  | Unassigned                 | full            | 1,900                   | irrigation (hand set)                                                                                                                   |
|                                                                                     |                            | full            | 230                     | hand harvesting, hand pruning, scouting, container moving, hand weeding, transplanting, grafting, propagating, pinching, tying/training |



**Table 10. Anticipated Post-Application Activities and Dermal Transfer Coefficients.**

| Proposed Crops                                                     | Policy Crop Group Category                          | Foliage Density | Transfer Coefficients | Activities                     |
|--------------------------------------------------------------------|-----------------------------------------------------|-----------------|-----------------------|--------------------------------|
|                                                                    |                                                     |                 | cm <sup>2</sup> /hr   |                                |
| Commercially Grown Outdoor Ornamentals (Field- or Container-Grown) | <i>Tree, "fruit," evergreen</i><br>(Christmas tree) | full            | 1,900                 | irrigation (hand set)          |
|                                                                    |                                                     | full            | 1,400                 | harvesting                     |
|                                                                    |                                                     | full            | 580                   | scouting, shaping              |
|                                                                    |                                                     | min             | 230                   | transplanting                  |
|                                                                    |                                                     | full            | 100                   | hand weeding, grading/tagging, |

#### Equations/Calculations

The following equations were used to calculate risk estimates for workers performing post-application activities:

$$DFR_t (\mu\text{g}/\text{cm}^2) = AR (\text{lb ai}/\text{acre}) \times F \times (1-D)^t \times 4.54\text{E}8 \mu\text{g}/\text{lb} \times 2.47\text{E}-8 \text{ acre}/\text{cm}^2$$

Where:

- DFR<sub>t</sub> = dislodgeable foliage residue on day "t" (μg/cm<sup>2</sup>),
- AR = application rate (lb ai/acre),
- F = fraction of ai retained on foliage (unitless), and
- D = fraction of residue that dissipates daily (unitless).

$$DD_t (\text{mg}/\text{kg}/\text{day}) = \frac{DFR_t (\mu\text{g}/\text{cm}^2) \times 1\text{E}-3 \text{ mg}/\mu\text{g} \times TC (\text{cm}^2/\text{hr}) \times DA (1.8\%) \times ET (\text{hrs})}{BW (\text{kg})}$$

Where:

- DD<sub>t</sub> = daily dermal dose on day "t,"
- t = number of days after application day (days),
- DFR<sub>t</sub> = dislodgeable foliage residue on day "t" (μg/cm<sup>2</sup>),
- TC = transfer coefficient (cm<sup>2</sup>/hr),
- DA = dermal absorption factor (unitless),
- ET = exposure time (hr/day), and
- BW = body weight (kg).

$$\text{Margin of Exposure (MOE)} = \frac{\text{NOAEL (mg}/\text{kg}/\text{day})}{\text{Average Daily Dose (mg}/\text{kg}/\text{day})}$$

Where:

- MOE = Margin of exposure value used by HED to represent risk or how close a chemical exposure is to being a concern (unitless),
- ADD = Average daily dose (ADD) is absorbed dose received from exposure to pesticide, and
- NOAEL = Dose level in a toxicity study, where no observed adverse effects occurred in the study.

## 5.2.2 Post-Application Dermal Exposure and Risk Estimates

The post-application exposure associated with agricultural crops is summarized in Table 11. For short-term exposure duration, all scenarios resulted in MOEs greater than short-term LOC of 300 (ranging from 570 to 11,000) on day 0 (12 hours after application) and, therefore, are not of concern to HED. For intermediate-term exposure durations, risk estimates are less than the intermediate-term LOC of 1000 and are of concern on day 0 (12 hours after application).

| Table 11. Short- and Intermediate-Term Post-Application Exposures and Risk Estimates for Emamectin Benzoate for Commercially Grown Outdoor Ornamentals (Field- and Container-Grown) |                      |                      |                           |                                  |                               |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|----------------------|---------------------------|----------------------------------|-------------------------------|
| Activity                                                                                                                                                                            | Transfer Coefficient | Days After Treatment | DFR <sup>a</sup>          | Daily Dermal Dose <sup>b</sup>   | Dermal MOE <sup>c</sup>       |
|                                                                                                                                                                                     |                      |                      | $\mu\text{g}/\text{cm}^2$ | $\text{mg}/\text{kg}/\text{day}$ | ST LOC = 300<br>IT LOC = 1000 |
| irrigation (hand set)                                                                                                                                                               | 1,900                | 0<br>(12 hours)      | 0.0336                    | 0.00013                          | 570                           |
|                                                                                                                                                                                     |                      | 1                    | 0.0303                    | 0.00012                          | 630                           |
|                                                                                                                                                                                     |                      | 2                    | 0.0272                    | 0.00011                          | 700                           |
|                                                                                                                                                                                     |                      | 3                    | 0.0245                    | 0.000096                         | 780                           |
|                                                                                                                                                                                     |                      | 4                    | 0.0221                    | 0.000086                         | 870                           |
|                                                                                                                                                                                     |                      | 5                    | 0.0199                    | 0.000078                         | 970                           |
|                                                                                                                                                                                     |                      | 6                    | 0.0179                    | 0.000070                         | 1,100                         |
| harvesting                                                                                                                                                                          | 1,400                | 0<br>(12 hours)      | 0.0336                    | 0.000097                         | 770                           |
|                                                                                                                                                                                     |                      | 1                    | 0.0303                    | 0.000087                         | 860                           |
|                                                                                                                                                                                     |                      | 2                    | 0.0272                    | 0.000078                         | 960                           |
|                                                                                                                                                                                     |                      | 3                    | 0.0245                    | 0.000071                         | 1,100                         |
| scouting, shaping                                                                                                                                                                   | 580                  | 0<br>(12 hours)      | 0.0336                    | 0.000040                         | 1,900                         |
| hand harvesting, hand pruning, scouting, container moving, hand weeding, transplanting, grafting, propagating, pinching, tying/training                                             | 230                  | 0<br>(12 hours)      | 0.0336                    | 0.000016                         | 4,700                         |
| hand weeding, grading/tagging,                                                                                                                                                      | 100                  | 0<br>(12 hours)      | 0.0336                    | 0.0000069                        | 11,000                        |

a DFR ( $\mu\text{g}/\text{cm}^2$ ) = application rate (0.015 lb ai/acre) x fraction of application rate dislodgeable on day 0 (20%) x (1 - fraction of residue that dissipates daily 10%)<sup>1</sup> x 4.54E8  $\mu\text{g}/\text{lb}$  x 2.47E-8 acre/ $\text{cm}^2$ .

b Short-/Intermediate-Term Daily Dermal Dose = [DFR ( $\mu\text{g}/\text{cm}^2$ ) x Transfer Coefficient x 0.001  $\text{mg}/\mu\text{g}$  x 8 hrs/day x dermal absorption 1.8%] ÷ body weight (70 kg adult).

c Short-/Intermediate-Term MOE = NOAEL ( $\text{mg}/\text{kg}/\text{day}$ )/Daily Dermal Dose ( $\text{mg}/\text{kg}/\text{day}$ ). ST/IT NOAEL = 0.075  $\text{mg}/\text{kg}/\text{day}$ .

### Restricted Entry Interval

Typically, under WPS for Agricultural Pesticides, active ingredients classified as acute Toxicity Category III or IV for Acute Dermal, Eye Irritation, and Primary Skin Irritation are assigned a 12-hour REI. However, since the intermediate-term post-application risk estimates were of concern on day 0 (12 hours following application), the 12-hour REI on the proposed label is unacceptable and the REI for ornamentals must be based on post-application assessment. For intermediate-term exposure durations, risk estimates for irrigation are not of concern on day 6, and risk estimates for harvesting are not of concern on day 3. Thus, an REI of 6 days is recommended for outdoor-grown ornamental plants in commercial nursery production.



### **5.2.3 Occupational Post-Application Inhalation Exposure**

Based on the Agency's current practices, a quantitative occupational post-application inhalation exposure assessment was not performed for emamectin benzoate at this time because the chemical has low vapor pressure ( $3.0 \times 10^{-8}$  mm Hg at 21 °C) and is applied at a low rate (0.015 lb ai/A). However, there are multiple potential sources of post-application inhalation exposure to individuals performing post-application activities in previously treated fields. These potential sources include volatilization of pesticides and resuspension of dusts and/or particulates that contain pesticides. The Agency sought expert advice and input on issues related to volatilization of pesticides from its Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (SAP) in December 2009. The Agency received the SAP's final report on March 2, 2010 (<http://www.epa.gov/scipoly/SAP/meetings/2009/120109meeting.html>) and is in the process of evaluating the SAP report as well as available post-application inhalation exposure data generated by the Agricultural Reentry Task Force. The Agency may, as appropriate, develop policies and procedures to identify the need for and, subsequently, the way to incorporate occupational post-application inhalation exposure into the Agency's risk assessments. If new policies or procedures are put into place, the Agency may revisit the need for a quantitative occupational post-application inhalation exposure assessment for emamectin benzoate.

### **6.0 Label Recommendation**

The label must indicate the required PPE for handheld applications (i.e. applications via backpack sprayers or manually pressurized handwands).



**Recommendation of Division Directors  
Negotiated Due Dates**

|                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                             |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| <b>Decision #:</b> D449308                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Registration #:</b> 100-RURR                                                                                                                                                                                                                                                                                                                                            | <b>Petition #:</b> —                                                                                        |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                             |
| <input checked="" type="checkbox"/> See page 2 for additional registration entries                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                             |
| <b>Chemical Name:</b> emamectin benzoate                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                             |
| <b>Fee Category:</b> R230                                                                                                                                                                                                                                                                                                                                                                                                                          | <b>PRIA Decision Time Frame:</b> 15 months                                                                                                                                                                                                                                                                                                                                 |                                                                                                             |
| <b>Submitted by:</b> Thomas Harris                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Branch:</b> OCS/P/OPP/RD                                                                                                                                                                                                                                                                                                                                                | <b>Date:</b> 04/29/2013                                                                                     |
| <b>Company:</b> Syngenta Crop Protection                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                             |
| <b>Original PRIA Due Date:</b> 09/08/2012                                                                                                                                                                                                                                                                                                                                                                                                          | <b>Proposed New PRIA Due Date:</b> 05/03/2013                                                                                                                                                                                                                                                                                                                              |                                                                                                             |
| <b>Previous Negotiated Due Dates:</b> 10/25/2012    12/20/2012    03/20/2012    04/22/2013                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                             |
| <b>Is the "Fix" in-house?</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> n/a <b>If not, date "Fix" expected:</b> 04/10/2012                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                             |
| <b>Negotiated Due Date Reason:</b>                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                             |
| <b>Additional Data Required</b>                                                                                                                                                                                                                                                                                                                                                                                                                    | <input type="checkbox"/> Product Chemistry <input type="checkbox"/> Toxicology <input type="checkbox"/> Acute Tox <input type="checkbox"/> Environmental<br><input type="checkbox"/> Efficacy <input type="checkbox"/> Ecological <input type="checkbox"/> Residue <input type="checkbox"/> Other                                                                          |                                                                                                             |
| <b>Data Deficiencies</b>                                                                                                                                                                                                                                                                                                                                                                                                                           | <input type="checkbox"/> Product Chemistry <input type="checkbox"/> Acute Tox <input type="checkbox"/> Efficacy <input type="checkbox"/> Residue <input type="checkbox"/> Toxicology<br><input type="checkbox"/> Environmental <input type="checkbox"/> Ecological <input type="checkbox"/> Labeling <input type="checkbox"/> Other <input type="checkbox"/> Not Submitted |                                                                                                             |
| <b>Late Risk Assessment</b>                                                                                                                                                                                                                                                                                                                                                                                                                        | <input type="checkbox"/> Human Health <input type="checkbox"/> Ecological                                                                                                                                                                                                                                                                                                  |                                                                                                             |
| <b>Interim Consideration</b>                                                                                                                                                                                                                                                                                                                                                                                                                       | <input type="checkbox"/> Agency Initiated <input type="checkbox"/> Registrant Initiated                                                                                                                                                                                                                                                                                    |                                                                                                             |
| <input type="checkbox"/> CSF                                                                                                                                                                                                                                                                                                                                                                                                                       | <input type="checkbox"/> Public Process                                                                                                                                                                                                                                                                                                                                    | <input type="checkbox"/> Risk Issues Environmental <input type="checkbox"/> Risk Issues Human Health        |
| <input type="checkbox"/> Impurities Review                                                                                                                                                                                                                                                                                                                                                                                                         | <input checked="" type="checkbox"/> Label                                                                                                                                                                                                                                                                                                                                  | <input type="checkbox"/> Administrative-FR Notice <input checked="" type="checkbox"/> Other – Comment Field |
| <b>Summary of Deficiency Type(s):</b> <input type="checkbox"/> Not Submitted (N) <input type="checkbox"/> Deficiencies (D)                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                             |
| <b>Product Chemistry:</b> <input type="checkbox"/> <b>Acute Tox:</b> <input type="checkbox"/> <b>Efficacy:</b> <input type="checkbox"/> <b>Labeling:</b> <input checked="" type="checkbox"/> <b>Ecological Data:</b> <input type="checkbox"/> <b>Other (describe):</b> <input type="checkbox"/>                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                             |
| <b>Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):</b><br>Phone call with Syngenta 3/28/13, email reminders to Syngenta 4/10/13, 4/17/13, 4/22/13 that revised label, negotiation, or withdrawal needed. Email (attached) from Syngenta 4/22/13 5:09 pm requesting PRIA extension while they work on label. [Same email withdrew cucurbit label actions.] |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                             |
| <b>"75 Day" Letter sent?</b> <input type="checkbox"/> Yes/Date sent <input type="checkbox"/> No and reason for none? <i>Add comments on page 2</i>                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                             |
| <b>Rationale for Proposed Due Date:</b> Syngenta wants more time to consider HED required label changes (PPE)                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                             |
| <b>Registrant notified that this is the last negotiation?</b> <input type="checkbox"/> Yes <input type="checkbox"/> Not Applicable                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                             |
| <b>Approve:</b> <input checked="" type="checkbox"/> <b>Disapprove:</b> <input type="checkbox"/>                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                             |
| <b>If disapproved, action to be taken:</b>                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                             |
| <b>OD or DOD Signature:</b>                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                            | <b>Date:</b>                                                                                                |

| Decision #: | Registration #: | Petition #: |
|-------------|-----------------|-------------|
|             |                 |             |
|             |                 |             |

**Issue(s) (describe in detail):**

PREVIOUSLY: Originally, two separate actions were submitted within about a month of each other: a new use on cucurbits group 9 R170 and a new use on ornamentals R230. Since HED and EFED decided to run the risk assessments for the two new uses together the PRIA dates were synchronized and have both been negotiated several times since then.

Eventually, the cucurbit tolerance was set on 3/27/13 but the cucurbit labels were withdrawn on 4/22/13 since the registrant did not want to accept the HED required PPE.

THIS NEGOTIATION: Registrant wishes additional 2 weeks to revise ornamental label to add labeling required by HED risk assessment.

**WHY THE DELAY IN SENDING THIS NEGOTIATION FORWARD:**

Registrant negotiation request submitted at 5:09 PM on the PRIA due date 4/22/13 (attached). Initial RD reaction was to stamp label as accept with label comments and complete the action on the due date. However, while reviewing the HED risk assessment to make sure all label corrections a conundrum was discovered. Since no dislodgeable foliar residue (DFR) study had been submitted, the occupational post-application risk was done using screening level assumptions. With these assumptions the post-app dermal risk MOE is greater than the LOC and therefore acceptable. However, since the MOE was not at least 4X the LOC, HED policy is that a DFR study must be submitted and the memo lists that as a data deficiency. Given the current policy on conditional registrations it is unclear how to handle this situation.

Note 1: The HED risk assesment also mentions four other data deficiencies. However, these have either been fulfilled, waived, submitted with review delayed until Registration Review, or final determination of whether study is even needed (and test animal to use) deferred until Registration Review. RD has requested an HED updated memo noting these facts and stating whether there are still any data deficiencies required to approve the ornamental new use request.

Note 2: The label revisions are almost complete so the label could be accepted without label comments.

**Comment(s):**

# Audit Trail for

## Recommendation of Division Directors Negotiated Due Dates

**PDF Name:** PRIAv5.pdf

**Form Number:** PRIA

**Document Identifier:** PRIA-13119182536-TH



# \*Personal privacy information\*

**Harris,Thomas**

---

**From:** john.abbott@syngenta.com  
**Sent:** Monday, April 22, 2013 6:55 PM  
**To:** Harris,Thomas; tammy.tyler@syngenta.com  
**Subject:** Re: NEED IMMEDIATELY Monday 4/22/13: FW: Enamectin - cucurbits and ornamentals

Tom

Just now picked up your message. Call my mobile if we need to chat ( [REDACTED] )  
Yes, please withdraw cucurbits for. 100-1270 along with 100-904.

For the ornamentals, we will accept the label changes noted and the PRIA extension request was intended to allow time for the review and approval of the revised label. We will submit the revised label asap to insure you have adequate time. We are interested in having the Agency review the ornamental label as part of the review of the CF-1 mouse rationale and will make the appropriate submission to accomplish this goal.  
Hope this makes sense.

Thanks

John

Sent by Blackberry: [REDACTED]

---

**From:** Harris,Thomas <harris.thomas@epa.gov>  
**To:** Abbott John USGR  
**Sent:** Mon Apr 22 18:02:57 2013  
**Subject:** NEED IMMEDIATELY Monday 4/22/13: FW: Enamectin - cucurbits and ornamentals

John,

Hoping this gets to you via Blackberry or something. Two items need immediate attention:

- 1) CUCURBITS: I just sent an email to Tammy about this and called her but I think she has probably gone for the day. I need a confirmation from Syngenta that you want to withdraw the emamectin cucurbit actions for both 100-904 (end use) and 100-1270 (technical). The email below does not mention 100-1270.
- 2) ORNAMENTALS: The negotiation for 100-RURR is another issue but I don't know there's much we can do about that. It is too late to process a negotiation request; that takes at least 1-2 full days. I am assuming from your request for a two week extension that your intention is to adjust the ornamental label to a) drop aerial application so no water soluble packaging is needed, b) add the PPE per HED for mixer/loaders for ground and airblast; and c) require close cabs for airblast application. If that's correct, then we'll have to wind up approving the label after the PRIA date. If that is not your intention then you probably need to withdraw the ornamental application for 100-RURR. Please let me know more info about what you planned to do with the ornamental label in two weeks (actually, one week – I need some time to review and stamp it) OR state in an email that you wish to withdraw the application.

Thanks!

Tom Harris  
EPA/OCSP/OPP/RD  
voice: (703) 308-9423  
fax: (703) 308-0029  
harris.thomas@epa.gov

**From:** Harris, Thomas  
**Sent:** Monday, April 22, 2013 5:35 PM  
**To:** 'tammy.tyler@syngenta.com'  
**Cc:** tom.parshley@syngenta.com  
**Subject:** RE: Enamectin - cucurbits and ornamentals

Tammy,

There is also a pending action on the technical 100-1270 to add cucurbits. I need an email from you withdrawing that as well.

Tom Harris  
EPA/OCSPP/OPP/RD  
voice: (703) 308-9423  
fax: (703) 308-0029  
[harris.thomas@epa.gov](mailto:harris.thomas@epa.gov)

---

**From:** [tammy.tyler@syngenta.com](mailto:tammy.tyler@syngenta.com) [<mailto:tammy.tyler@syngenta.com>]  
**Sent:** Monday, April 22, 2013 5:09 PM  
**To:** Harris, Thomas  
**Cc:** [tom.parshley@syngenta.com](mailto:tom.parshley@syngenta.com)  
**Subject:** Enamectin - cucurbits and ornamentals

Hello Tom,  
Syngenta is withdrawing the current action for 100-904, for the new use of Proclaim Insecticide on cucurbits. We would like to request a PRIA extension on 100-RURR for use on ornamentals to May 3, 2013. Please contact me if you have any questions.  
Best regards,  
Tammy

---

Tammy Tyler, Ph.D.  
Regulatory Affairs  
Fungicide & Insecticide



410 Swing Rd  
Greensboro, NC  
27409  
USA

phone 336-632-6055  
fax 336-632-5688  
mobile [REDACTED]

---

*This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.*

\*\*\*\*\* ATTACHMENT NOT DELIVERED \*\*\*\*\*

This Email message contained an attachment named  
image001.jpg



| Recommendation of Division Directors<br>Negotiated Due Dates                                                                                                                                                                                          |                                                                                         |                                                    |                                                                                                         |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|----------------------------------------------------|---------------------------------------------------------------------------------------------------------|
| Decision #: D452137                                                                                                                                                                                                                                   |                                                                                         | Registration #: 100-904                            |                                                                                                         |
| D452134                                                                                                                                                                                                                                               |                                                                                         | 100-1270                                           |                                                                                                         |
| D452138                                                                                                                                                                                                                                               |                                                                                         | 1E7904                                             |                                                                                                         |
| <input checked="" type="checkbox"/> See page 2 for additional registration entries                                                                                                                                                                    |                                                                                         |                                                    |                                                                                                         |
| Chemical Name: emamectin benzoate                                                                                                                                                                                                                     |                                                                                         |                                                    |                                                                                                         |
| Fee Category: R170, R230                                                                                                                                                                                                                              |                                                                                         | PRIA Decision Time Frame: 15 months                |                                                                                                         |
| Submitted by: Thomas Harris                                                                                                                                                                                                                           |                                                                                         | Branch: OCSPP/OPP/RD                               | Date: 03/18/2013                                                                                        |
| Company: Syngenta Crop Protection                                                                                                                                                                                                                     |                                                                                         |                                                    |                                                                                                         |
| Original PRIA Due Date: 10/25/2012                                                                                                                                                                                                                    |                                                                                         | Proposed New PRIA Due Date: 04/22/2012             |                                                                                                         |
| Previous Negotiated Due Dates: 10/25/2012      12/20/2012      03/20/2012                                                                                                                                                                             |                                                                                         |                                                    |                                                                                                         |
| Is the "Fix" in-house? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> n/a                                                                                                                               |                                                                                         | If not, date "Fix" expected: 04/10/2012            |                                                                                                         |
| Negotiated Due Date Reason:                                                                                                                                                                                                                           |                                                                                         |                                                    |                                                                                                         |
| Additional Data Required                                                                                                                                                                                                                              | <input type="checkbox"/> Product Chemistry                                              | <input type="checkbox"/> Toxicology                | <input type="checkbox"/> Acute Tox <input type="checkbox"/> Environmental                               |
|                                                                                                                                                                                                                                                       | <input type="checkbox"/> Efficacy                                                       | <input type="checkbox"/> Ecological                | <input type="checkbox"/> Residue <input type="checkbox"/> Other                                         |
| Data Deficiencies                                                                                                                                                                                                                                     | <input type="checkbox"/> Product Chemistry                                              | <input type="checkbox"/> Acute Tox                 | <input type="checkbox"/> Efficacy <input type="checkbox"/> Residue <input type="checkbox"/> Toxicology  |
|                                                                                                                                                                                                                                                       | <input type="checkbox"/> Environmental                                                  | <input type="checkbox"/> Ecological                | <input type="checkbox"/> Labeling <input type="checkbox"/> Other <input type="checkbox"/> Not Submitted |
| Late Risk Assessment                                                                                                                                                                                                                                  | <input type="checkbox"/> Human Health <input type="checkbox"/> Ecological               |                                                    |                                                                                                         |
| Interim Consideration                                                                                                                                                                                                                                 | <input type="checkbox"/> Agency Initiated <input type="checkbox"/> Registrant Initiated |                                                    |                                                                                                         |
| <input type="checkbox"/> CSF                                                                                                                                                                                                                          | <input type="checkbox"/> Public Process                                                 | <input type="checkbox"/> Risk Issues Environmental | <input type="checkbox"/> Risk Issues Human Health                                                       |
| <input type="checkbox"/> Impurities Review                                                                                                                                                                                                            | <input checked="" type="checkbox"/> Label                                               | <input type="checkbox"/> Administrative-FR Notice  | <input type="checkbox"/> Other – Comment Field                                                          |
| Summary of Deficiency Type(s): <input type="checkbox"/> Not Submitted (N) <input type="checkbox"/> Deficiencies (D)                                                                                                                                   |                                                                                         |                                                    |                                                                                                         |
| Product Chemistry: <input type="checkbox"/> Acute Tox: <input type="checkbox"/> Efficacy: <input type="checkbox"/> Labeling: <input checked="" type="checkbox"/> Ecological Data: <input type="checkbox"/> Other (describe): <input type="checkbox"/> |                                                                                         |                                                    |                                                                                                         |
| Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):                                                                                                              |                                                                                         |                                                    |                                                                                                         |
| Emails to Syngenta (1/24/13, 2/20/13), phone call (~3/7/13) to provide HED review including required label changes. Email from Syngenta (3/15/13) requesting PRIA extension while they work on label (attached).                                      |                                                                                         |                                                    |                                                                                                         |
| "75 Day" Letter sent? <input type="checkbox"/> Yes, Date sent <input type="checkbox"/> No and reason for none? Add comments on page 2                                                                                                                 |                                                                                         |                                                    |                                                                                                         |
| Rationale for Proposed Due Date: Syngenta wants more time to consider HED required label changes (PPE)                                                                                                                                                |                                                                                         |                                                    |                                                                                                         |
| Registrant notified that this is the last negotiation? <input type="checkbox"/> Yes <input type="checkbox"/> Not Applicable                                                                                                                           |                                                                                         |                                                    |                                                                                                         |
| Approve: <input type="checkbox"/>                                                                                                                                                                                                                     |                                                                                         | Disapprove: <input type="checkbox"/>               |                                                                                                         |
| If disapproved, action to be taken:                                                                                                                                                                                                                   |                                                                                         |                                                    |                                                                                                         |
| OD or DOD Signature:                                                                                                                                                                                                                                  |                                                                                         |                                                    | Date:                                                                                                   |



|                            |                                 |                        |
|----------------------------|---------------------------------|------------------------|
| <b>Decision #:</b> D449308 | <b>Registration #:</b> 100-RURR | <b>Petition #:</b> --- |
|                            |                                 |                        |
|                            |                                 |                        |

**Issue(s) (describe in detail):**

FYI: cucurbits is R170, ornamentals is R230

**PREVIOUSLY:**

a) 100-RURR ornamentals had been negotiated from original PRIA date 9/8/12 to negotiated 10/25/12 to match cucurbits since the two uses are being analyzed together (but had been submitted slightly different times hence the difference in the original due dates).

b) All actions extended to 12/20/12 to allow for re-work on HED risk assessment to address issues raised by OGC during review of FR final rule. HED had to rewrite risk assessment and RD rewrote FR final rule before next OGC review.

c) Extension to 3/20/13 was requested to allow for more extensive rewrite by HED (initial rewrite did not satisfy OGC concerns). Also, HED worker exposure analyses were redone using additional data (task force) and refinements in assumptions. New FR final rule written and is now almost ready for publication. FYI, ornamentals is now the drinking water driver rather than food crops.

**THIS NEGOTIATION:**

d) Syngenta is requesting more time to consider labeling options outlined in HED risk analysis. HED required significant additional PPE (respirator or water soluble packaging) to reduce mixer/loader risk.

**Comment(s):**

**Harris, Thomas**

---

**From:** tammy.tyler@syngenta.com  
**Sent:** Friday, March 15, 2013 12:21 PM  
**To:** Harris, Thomas  
**Cc:** Charles.Levey@syngenta.com; john.abbott@syngenta.com; tom.parshley@syngenta.com  
**Subject:** RE: emamectin cuke, ornamental: need revised labels

Hello Tom,

Syngenta is requesting an extension of this PRIA date to April 22, 2013 for these aba submissions on cucurbits and ornamentals.

Please let me know if you have any questions.

Happy Friday,

Tammy

---

**From:** Harris, Thomas [mailto:harris.thomas@epa.gov]  
**Sent:** Thursday, March 07, 2013 3:26 PM  
**To:** Abbott John USGR  
**Cc:** Levey Charles USGR; Tyler Tammy USGR  
**Subject:** emamectin cuke, ornamental: need revised labels

Reminder, the ball is in your court at the moment. The attached risk assessment has several label changes on PPE for both the cucurbit and ornamental labels. PRIA due date is 3/20/13.

FR final rule has been sent for typesetting and I believe it will be signed despite OGC concerns about whether cumulative should be done (I believe our answer is no at this time).

-Tom

---

**From:** Harris, Thomas  
**Sent:** Wednesday, February 20, 2013 3:25 PM  
**To:** 'charles.levey@syngenta.com'  
**Subject:** emamectin cucumber, ornamental risk assessment

Chuck,

Since you gave me a card your email is the only one I could easily find. Hope my address book transfers soon!

Please forward this email to Tammy and John. There are a number of label changes to be made (eg. See page 11). The longer REIs in the original draft went away (discussed below) but I see there is still significant PPE required.

Tom

---

**From:** Thomas Harris [mailto:harris.thomas@epamail.epa.gov]  
**Sent:** Wednesday, February 20, 2013 3:16 PM  
**To:** Harris, Thomas  
**Subject:** Fw: 'mectin stuff'

Tom Harris  
EPA/OCSP/OPP/RD/IRB



voice: (703) 308-9423

fax: (703) 308-0029

[harris.thomas@epa.gov](mailto:harris.thomas@epa.gov)

visit <http://www.epa.gov/pesticides>

----- Forwarded by Thomas Harris/DC/USEPA/US on 02/20/2013 03:15 PM -----

From: Thomas Harris/DC/USEPA/US

To: [carolyn.brinkley@syngenta.com](mailto:carolyn.brinkley@syngenta.com), [tom.parshley@syngenta.com](mailto:tom.parshley@syngenta.com)

Cc: Barbara Madden/DC/USEPA/US@EPA, Andrew Ertman/DC/USEPA/US@EPA

Date: 01/24/2013 03:40 PM

Subject: 'mectin stuff'

---

Following up on our phone conversation yesterday:

**1) new avermectin SC adjuvant amendments**

Found them. I now have these four non-PRIA Fast Track amendments and will handle these (100-1350, -1351, -1408, -1439). Are these routine or do you have a critical time crunch?

**2) emamectin cucurbits & ornamentals - what's different in the ORE review?**

I talked with Nancy Tsaour. There is an extra safety factor added in the ORE due to lack of 28-day inhalation study. I looked in my folder on that topic and I think the last thing we worked on was a protocol review. I think you're working on running the study.

**3) emamectin cucurbits & ornamentals - revised risk assessment**

Here it is. It has been signed so it's final, at least for the moment. I think if there are still OGC issues they would be handled during processing of the final rule that Andy Ertman is working on.

*(See attached file: HED.122806.20130109.D393837.revised RA memo.pdf)*

Tom Harris

EPA/OCSP/OPP/RD/IRB

voice: (703) 308-9423

fax: (703) 308-0029

[harris.thomas@epa.gov](mailto:harris.thomas@epa.gov)

visit <http://www.epa.gov/pesticides>

---

*This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.*



**Harris,Thomas**

---

**From:** Marty Monell [Monell.Marty@epamail.epa.gov] on behalf of Workflow Messenger  
[Workflow\_Messenger@epamail.epa.gov]  
**Sent:** Tuesday, March 19, 2013 6:44 AM  
**To:** Monell, Marty; Harris,Thomas  
**Subject:** Recommendation of Division Directors Negotiated Due Dates has been completed by Marty Monell.

Recommendation of Division Directors Negotiated Due Dates has been completed by Marty Monell.

Author: Thomas Harris  
Chemical: emamectin benzoate  
Form Date: 03/18/2013  
Decision #: D452137  
D452134  
D452138  
Registration #: 100-904  
100-1270

---  
Petition #: ---

---  
1E7904  
Original PRIA Due Date: 10/25/2012  
Previous Negotiated Due Dates: 10/25/2012, 12/20/2012, 03/20/2012,  
Proposed New PRIA Due Date: 04/22/2012

Click on this link to access this form:

<https://webforms.epa.gov/webforms/webformsadmin.nsf/formOpen?OpenAgent&UNID=E318FD14BB2A75FA85257B32005A7F66&USERDB=webforms/webformsapp.nsf>

Click on this link to access all your forms:

<https://webforms.epa.gov/webforms/webformsapp.nsf>

| Recommendation of Division Directors<br>Negotiated Due Dates                                                                                                                                                                                              |                                            |                                                    |                                                           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|----------------------------------------------------|-----------------------------------------------------------|
| Decision #: D452137                                                                                                                                                                                                                                       |                                            | Registration #: 100-904                            |                                                           |
| D452134                                                                                                                                                                                                                                                   |                                            | 100-1270                                           |                                                           |
| D452138                                                                                                                                                                                                                                                   |                                            | 1E7904                                             |                                                           |
| <input checked="" type="checkbox"/> See page 2 for additional registration entries                                                                                                                                                                        |                                            |                                                    |                                                           |
| Chemical Name: emamectin benzoate                                                                                                                                                                                                                         |                                            |                                                    |                                                           |
| Fee Category: R170, R230                                                                                                                                                                                                                                  |                                            | PRIA Decision Time Frame: 15 months                |                                                           |
| Submitted by: Thomas                                                                                                                                                                                                                                      |                                            | Harris                                             |                                                           |
| Branch: OCSPP/OPP/RD                                                                                                                                                                                                                                      |                                            | Date: 12/20/2012                                   |                                                           |
| Company: Syngenta Crop Protection                                                                                                                                                                                                                         |                                            |                                                    |                                                           |
| Original PRIA Due Date: 10/25/2012                                                                                                                                                                                                                        |                                            | Proposed New PRIA Due Date: 03/20/2013             |                                                           |
| Previous Negotiated Due Dates: 10/25/2012      12/20/2012                                                                                                                                                                                                 |                                            |                                                    |                                                           |
| Is the "Fix" in-house? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> n/a      If not, date "Fix" expected:                                                                                                 |                                            |                                                    |                                                           |
| Negotiated Due Date Reason:                                                                                                                                                                                                                               |                                            |                                                    |                                                           |
| Additional Data Required                                                                                                                                                                                                                                  | <input type="checkbox"/> Product Chemistry | <input type="checkbox"/> Toxicology                | <input type="checkbox"/> Acute Tox                        |
|                                                                                                                                                                                                                                                           | <input type="checkbox"/> Efficacy          | <input type="checkbox"/> Ecological                | <input type="checkbox"/> Residue                          |
| Data Deficiencies                                                                                                                                                                                                                                         | <input type="checkbox"/> Product Chemistry | <input type="checkbox"/> Acute Tox                 | <input type="checkbox"/> Efficacy                         |
|                                                                                                                                                                                                                                                           | <input type="checkbox"/> Environmental     | <input type="checkbox"/> Ecological                | <input type="checkbox"/> Labeling                         |
| Late Risk Assessment                                                                                                                                                                                                                                      | <input type="checkbox"/> Human Health      | <input type="checkbox"/> Ecological                | <input type="checkbox"/> Toxicology                       |
| Interim Consideration                                                                                                                                                                                                                                     | <input type="checkbox"/> Agency Initiated  | <input type="checkbox"/> Registrant Initiated      | <input type="checkbox"/> Not Submitted                    |
| <input type="checkbox"/> CSF                                                                                                                                                                                                                              | <input type="checkbox"/> Public Process    | <input type="checkbox"/> Risk Issues Environmental | <input type="checkbox"/> Risk Issues Human Health         |
| <input type="checkbox"/> Impurities Review                                                                                                                                                                                                                | <input type="checkbox"/> Label             | <input type="checkbox"/> Administrative-FR Notice  | <input checked="" type="checkbox"/> Other – Comment Field |
| Summary of Deficiency Type(s): <input type="checkbox"/> Not Submitted (N) <input type="checkbox"/> Deficiencies (D)                                                                                                                                       |                                            |                                                    |                                                           |
| Product Chemistry: <input type="checkbox"/> Acute Tox: <input type="checkbox"/> Efficacy: <input type="checkbox"/> Labeling: <input type="checkbox"/> Ecological Data: <input type="checkbox"/> Other (describe): <input type="checkbox"/>                |                                            |                                                    |                                                           |
| Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):<br>Phone discussions and email. Copy of Syngenta 12/20/12, 8:37 am email stating concurrence is attached (.pdf). |                                            |                                                    |                                                           |
| "75 Day" Letter sent? <input type="checkbox"/> Yes, Date sent <input type="checkbox"/> No and reason for none? <i>Add comments on page 2</i>                                                                                                              |                                            |                                                    |                                                           |
| Rationale for Proposed Due Date: address issues in risk assessment raised by OGC; revised worker risk                                                                                                                                                     |                                            |                                                    |                                                           |
| Registrant notified that this is the last negotiation? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not Applicable                                                                                                                    |                                            |                                                    |                                                           |
| Approve: <input checked="" type="checkbox"/>                                                                                                                                                                                                              |                                            | Disapprove: <input type="checkbox"/>               |                                                           |
| If disapproved, action to be taken:                                                                                                                                                                                                                       |                                            |                                                    |                                                           |
| OD or DOD Signature: CN=William Jordan/OU=DC/O=USEPA/C=US                                                                                                                                                                                                 |                                            |                                                    | Date: 12/20/2012                                          |



|                            |                                 |                    |
|----------------------------|---------------------------------|--------------------|
| <b>Decision #:</b> D449308 | <b>Registration #:</b> 100-RURR | <b>Petition #:</b> |
|                            |                                 |                    |
|                            |                                 |                    |

**Issue(s) (describe in detail):**

FYI: cucurbits is R170, ornamentals is R230

PREVIOUSLY:


a) 100-RURR ornamentals had been negotiated from original PRIA date 9/8/12 to negotiated 10/25/12 to match cucurbits since the two uses are being analyzed together (but had come in slightly different times hence the difference in original due dates).

b) All actions extended to 12/20/12 to allow for re-work on HED risk assessment to address issues raised by OGC during review of FR final rule. HED will rewrite risk assessment, then RD will rewrite FR final rule, then both will be sent through OGC for concurrence again.

THIS NEGOTIATION:

c) Now requesting extension to 3/20/12. Initial rewrite by HED did not satisfy OGC concerns. More extensive HED rewrite being done. Also, HED worker exposure analyses being redone using additional data (task force) and refinements in assumptions. An entirely new FR final rule will need to be written, reviewed, and published before labels can be accepted. FYI, ornamentals is now the drinking water driver so ornamentals are linked to outcome of cucurbits.

**Comment(s):**

 RE: emamectin - request for extension of negotiated due date for cucurbits & ornamentals  
carolyn.brinkley

to:

Thomas Harris, tom.parshley

12/20/2012 12:32 PM

Cc:

John Hebert, Meredith Laws

Hide Details

From: <carolyn.brinkley@syngenta.com>

To: Thomas Harris/DC/USEPA/US@EPA, <tom.parshley@syngenta.com>

Cc: John Hebert/DC/USEPA/US@EPA, Meredith Laws/DC/USEPA/US@EPA

History: This message has been replied to.

Hi Tom,

In response to your message Syngenta requests that the EPA set March 20, 2013 as the new PRIA date for the pending applications for the registration of emamectin on ornamentals and on cucurbits.

Please call me if you need anything further.

Best regards,

Carolyn

---

**From:** harris.thomas@epamail.epa.gov [<mailto:harris.thomas@epamail.epa.gov>]

**Sent:** Monday, December 17, 2012 4:52 PM

**To:** Brinkley Carolyn USGR; Parshley Tom USGR

**Cc:** Hebert.John@epamail.epa.gov; Laws.Meredith@epamail.epa.gov

**Subject:** emamectin - request for extension of negotiated due date for cucurbits & ornamentals

Carolyn, Tom:

The purpose of this email is to request Syngenta's concurrence on re-negotiating the due date for the pending new uses of emamectin on cucurbits (1E7904, 100-1270, 100-904) and ornamentals (100-RURR).

These two new uses were originally submitted as separate PRIA actions (the cucurbits is actually an IR-4 proposal) a couple of months apart. Syngenta agreed to synchronize the due dates since the two actions were being analyzed together. Additional time was then added to allow the Agency to address an issue raised by



our lawyers during a review of the draft FR final rule. That issue (whether the 'mectins should be analyzed under cumulative review) is still being discussed to find a path forward but in the meantime I had started to address the label changes required by the risk assessment.

As they currently stand, the reviews institute several new restrictions to address worker exposure (water soluble packaging, multi-day REIs, additional PPE, et al). Two factors have created these new requirements: a) while the new uses follow the same individual rates as the registered crops they double the seasonal maximum quantity and therefore double the number of applications per season, and b) new task force data concerning exposure data. However, these new requirements are not unique to the two new uses. Indeed, they apply to many of the existing uses and many of the existing emamectin products. That lead us to rethink the timing of instituting these new restrictions. To facilitate across-the-board implementation we have decided to address the new exposure data during Registration Review along with the additional information being supplied during that process.

In order to do that, we need to rework all the existing human health reviews and risk assessment as well as a rewrite of the FR final rule. To that end, the Agency is requesting that we negotiate the due date out 3 months to March 20, 2013.

Please email me Syngenta's response to this new negotiated due date. Call me if you have any questions.

Thank you.

Tom Harris  
EPA/OPPTS/OPP/RD/IRB  
voice: (703) 308-9423  
fax: (703) 308-0029  
[harris.thomas@epa.gov](mailto:harris.thomas@epa.gov)  
visit <http://www.epa.gov/pesticides>

---

*This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.*

# Audit Trail for

## Recommendation of Division Directors Negotiated Due Dates

**PDF Name:** PRIAv5.pdf

**Form Number:** PRIA

**Document Identifier:** PRIA-12355124920-TH

SUBMITTED on 12/20/2012 at 12:51:15 PM by CN=Thomas Harris/OU=DC/O=USEPA/C=US

APPROVED on 12/20/2012 at 04:18:39 PM by CN=Meredith Laws/OU=DC/O=USEPA/C=US

APPROVED on 12/20/2012 at 04:51:27 PM by CN=Dan Rosenblatt/OU=DC/O=USEPA/C=US

APPROVED AND COMPLETED on 12/20/2012 at 04:56:14 PM by CN=William Jordan/OU=DC/O=USEPA/C=US



# Recommendation of Division Directors

## Negotiated Due Dates

|                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                             |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| <b>Decision #:</b> D452137                                                                                                                                                                                                                                                           | <b>Registration #:</b> 100-904                                                                                                                                                                                                                                                                                                                                             | <b>Petition #:</b> ---                                                                                      |
| D452134                                                                                                                                                                                                                                                                              | 100-1270                                                                                                                                                                                                                                                                                                                                                                   | ---                                                                                                         |
| D452138                                                                                                                                                                                                                                                                              | ---                                                                                                                                                                                                                                                                                                                                                                        | 1E7904                                                                                                      |
| <input checked="" type="checkbox"/> See page 2 for additional registration entries                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                             |
| <b>Chemical Name:</b> emamectin benzoate                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                             |
| <b>Fee Category:</b> R170, R230                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                            | <b>PRIA Decision Time Frame:</b> 15 months                                                                  |
| <b>Submitted by:</b> Thomas Harris                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                            | <b>Branch:</b> OCSPP/OPP/RD <b>Date:</b> 10/23/2012                                                         |
| <b>Company:</b> Syngenta Crop Protection                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                             |
| <b>Original PRIA Due Date:</b> 10/25/2012                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                            | <b>Proposed New PRIA Due Date:</b> 12/20/2012                                                               |
| <b>Previous Negotiated Due Dates:</b> 10/25/2012                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                             |
| <b>Is the "Fix" in-house?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> n/a                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                            | <b>If not, date "Fix" expected:</b>                                                                         |
| <b>Negotiated Due Date Reason:</b>                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                             |
| <b>Additional Data Required</b>                                                                                                                                                                                                                                                      | <input type="checkbox"/> Product Chemistry <input type="checkbox"/> Toxicology <input type="checkbox"/> Acute Tox <input type="checkbox"/> Environmental<br><input type="checkbox"/> Efficacy <input type="checkbox"/> Ecological <input type="checkbox"/> Residue <input type="checkbox"/> Other                                                                          |                                                                                                             |
| <b>Data Deficiencies</b>                                                                                                                                                                                                                                                             | <input type="checkbox"/> Product Chemistry <input type="checkbox"/> Acute Tox <input type="checkbox"/> Efficacy <input type="checkbox"/> Residue <input type="checkbox"/> Toxicology<br><input type="checkbox"/> Environmental <input type="checkbox"/> Ecological <input type="checkbox"/> Labeling <input type="checkbox"/> Other <input type="checkbox"/> Not Submitted |                                                                                                             |
| <b>Late Risk Assessment</b>                                                                                                                                                                                                                                                          | <input type="checkbox"/> Human Health <input type="checkbox"/> Ecological                                                                                                                                                                                                                                                                                                  |                                                                                                             |
| <b>Interim Consideration</b>                                                                                                                                                                                                                                                         | <input type="checkbox"/> Agency Initiated <input type="checkbox"/> Registrant Initiated                                                                                                                                                                                                                                                                                    |                                                                                                             |
| <input type="checkbox"/> CSF                                                                                                                                                                                                                                                         | <input type="checkbox"/> Public Process                                                                                                                                                                                                                                                                                                                                    | <input type="checkbox"/> Risk Issues Environmental <input type="checkbox"/> Risk Issues Human Health        |
| <input type="checkbox"/> Impurities Review                                                                                                                                                                                                                                           | <input type="checkbox"/> Label                                                                                                                                                                                                                                                                                                                                             | <input type="checkbox"/> Administrative-FR Notice <input checked="" type="checkbox"/> Other – Comment Field |
| <b>Summary of Deficiency Type(s):</b> <input type="checkbox"/> Not Submitted (N) <input type="checkbox"/> Deficiencies (D)                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                             |
| <b>Product Chemistry:</b> <input type="checkbox"/> <b>Acute Tox:</b> <input type="checkbox"/> <b>Efficacy:</b> <input type="checkbox"/> <b>Labeling:</b> <input type="checkbox"/> <b>Ecological Data:</b> <input type="checkbox"/> <b>Other (describe):</b> <input type="checkbox"/> |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                             |
| <b>Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):</b><br>Phone discussions and email. Copy of Syngenta 10/23/12, 5:35 pm email stating concurrence is attached (.pdf).                     |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                             |
| <b>"75 Day" Letter sent?</b> <input type="checkbox"/> Yes, Date sent <input type="checkbox"/> No and reason for none? Add comments on page 2                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                             |
| <b>Rationale for Proposed Due Date:</b> address issues in risk assessment raised by OGC                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                             |
| <b>Registrant notified that this is the last negotiation?</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not Applicable                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                             |
| <b>Approve:</b> <input type="checkbox"/>                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                            | <b>Disapprove:</b> <input type="checkbox"/>                                                                 |
| <b>If disapproved, action to be taken:</b>                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                             |
| <b>OD or DOD Signature:</b>                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                            | <b>Date:</b>                                                                                                |

|                            |                                 |                    |
|----------------------------|---------------------------------|--------------------|
| <b>Decision #:</b> D449308 | <b>Registration #:</b> 100-RURR | <b>Petition #:</b> |
|                            |                                 |                    |
|                            |                                 |                    |

**Issue(s) (describe in detail):**

PREVIOUSLY: 100-RURR ornamentals had been negotiated from original PRIA date 9/8/12 to negotiated 10/25/12 to match cucurbits since the two uses are being analyzed together (but had come in slightly different times hence the difference in original due dates).

Purpose of this negotiation is to allow for re-work on HED risk assessment to address issues raised by OGC during review of FR final rule. HED will rewrite risk assessment, then RD will rewrite FR final rule, then both will be sent through OGC for concurrence again.

FYI: cucurbits is R170, ornamentals is R230

**Comment(s):**





Syngenta agrees to new PRIA 12/20/12: - Enamectin cucurbits & commercial use ornamentals

carolyn.brinkley to: Thomas Harris

Cc: tom.parshley

10/23/2012 05:35 PM

From: <carolyn.brinkley@syngenta.com>  
To: Thomas Harris/DC/USEPA/US@EPA  
Cc: <tom.parshley@syngenta.com>

Hi Tom,

In response to your attached e-mail request to Tom Parshley and me, I'm sending you our reply to your request to change the PRIA date for the pending registration actions for emamectin . Specifics follow.

---

---

---

**I. EXTENSION OF PRIA DATE for PENDING EMAMECTIN ACTIONS**

This e-mail is to inform you that Syngenta Crop Protection LLC agrees to the extension of

the October 25, 2012 PRIA date to December 20, 2012 for the following emamectin actions:

A. CUCURBITS

a. Tolerance Petition cucurbits (Crop Group 9): PP#: 1E7904

i. Associated applications for  
registration

1. Proclaim® Insecticide (EPA Reg. No. 100-904): add  
directions for use for cucurbits (Crop Group 9)

2. Emamectin Benzoate Technical II (EPA Reg. No.  
100-1270): add cucurbits approved crops list

B. OUTDOOR COMMERCIAL USE -- ORNAMENTALS PRODUCTION

a. Application for New Product Registration / New Emamectin Use

i. New Product: Enfold™  
(100-RURR). ----- same formula as Proclaim Insecticide -



100-904 ----- New Use: This is the first use of emamectin for  
ornamentals

Best regards,

Carolyn F. Brinkley, Sr. Regulatory Product Manager / NAFTA Insecticides (  
emamectin, abamectin, cyromazine, profenofos, pymetrozine)

Syngenta Crop Protection

From: harris.thomas@epamail.epa.gov [mailto:harris.thomas@epamail.epa.gov]  
Sent: Monday, October 22, 2012 5:57 PM  
To: Brinkley Carolyn USGR  
Cc: Parshley Tom USGR  
Subject: RE: emamectin - request to extend due date for new uses on cucurbits and ornamentals

Just checking in. Actions are currently due Thursday (10/25) so I need to try to get paperwork filed at my  
end by Tuesday 10/23.

Tom Harris  
EPA/OPPTS/OPP/RD/IRB  
voice: (703) 308-9423  
fax: (703) 308-0029  
harris.thomas@epa.gov  
visit <http://www.epa.gov/pesticides>

—10/19/2012 02:24:34 PM—Hi Tom, will get back to you in a couple of days. From:  
harris.thomas@epamail.epa.gov [mailto:harris

From: <carolyn.brinkley@syngenta.com>  
To: Thomas Harris/DC/USEPA/US@EPA  
Cc: <tom.parshley@syngenta.com>  
Date: 10/19/2012 02:24 PM  
Subject: RE: emamectin - request to extend due date for new uses on cucurbits and ornamentals

Hi Tom, will get back to you in a couple of days.

From: harris.thomas@epamail.epa.gov [mailto:harris.thomas@epamail.epa.gov]  
Sent: Thursday, October 18, 2012 3:54 PM  
To: Brinkley Carolyn USGR; Parshley Tom USGR  
Cc: Hebert.John@epamail.epa.gov; Laws.Meredith@epamail.epa.gov; Madden.Barbara@epamail.epa.gov; Ertman.Andrew@epamail.epa.gov  
Subject: emamectin - request to extend due date for new uses on cucurbits and ornamentals

Carolyn, Tom:

We are wrapping up two pending new use PRIA actions for emamectin: cucurbits crop group 9 (100-1270, 100-904, 1E7904) and outdoor, commercial ornamental production (100-RURR). The PRIA due dates for all actions are 10/25/12. Unfortunately, we've hit a snag and need to extend the due dates.

As you are aware from your own assessment of these new uses, we are running very close to the limit of the risk cup. The initial OPP risk assessment using our default conservative assumptions did not pass. After several refinements including both percent crop treated and anticipated residues the new uses now pass at 98% of the risk cup. However, in reviewing the current human health risk assessment and draft FR final rule our lawyers have raised several objections. After some discussion we have found a way to satisfy their concerns but this requires rework of both the risk assessment and the resulting FR final rule. We still anticipate that the uses will be approved but need additional time to make these revisions.

To that end, we are requesting to extend the PRIA due dates for all actions from 10/25/12 to 12/20/12. Even with the upcoming holidays that should provide sufficient time for the revisions to the risk assessment and publication of the FR final rule. Please note that since both cucurbit and ornamentals uses are addressed in the same reviews we need to extend due dates for both new uses.

Please respond to this email letting me know if you agree with the negotiated due date of 12/20/12. Thank you.

Tom Harris  
EPA/OPPTS/OPP/RD/IRB  
voice: (703) 308-9423  
fax: (703) 308-0029  
harris.thomas@epa.gov  
visit <http://www.epa.gov/pesticides>

This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately.



and delete the original and any copies. Any use of the message by you is prohibited.

This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.



**Recommendation of Division Directors Negotiated Due Dates has been completed by William Jordan.**

**Workflow Messenger** to: William Jordan, Thomas Harris  
Sent by: William Jordan

10/24/2012 02:11 PM

Recommendation of Division Directors Negotiated Due Dates has been completed by William Jordan.

Author: Thomas Harris  
Chemical: emamectin benzoate  
Form Date: 10/23/2012  
Decision #: D452137  
D452134  
D452138  
Registration #: 100-904  
100-1270

---  
Petition #: ---  
---

1E7904  
Original PRIA Due Date: 10/25/2012  
Previous Negotiated Due Dates: 10/25/2012, , ,  
Proposed New PRIA Due Date: 12/20/2012

Click on this link to access this form:  
<https://webforms.epa.gov/webforms/webformsadmin.nsf/formOpen?OpenAgent&UNID=7D42C6C3F3DFB93C85257AA000730F15&USERDB=webforms/webformsapp.nsf>

Click on this link to access all your forms:  
<https://webforms.epa.gov/webforms/webformsapp.nsf>

| <b>Recommendation of Division Directors</b><br><b>Negotiated Due Dates</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                            |                                                    |                                                           |                                        |                                            |                                     |                                    |                                        |  |                                   |                                     |                                  |                                |                          |                                            |                                    |                                   |                                  |                                     |  |                                        |                                     |                                   |                                |                                        |                             |                                       |                                     |  |  |  |                              |                                           |                                               |  |  |  |                              |                                         |                                                    |                                                   |  |  |                                            |                                |                                                   |                                                           |  |  |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|----------------------------------------------------|-----------------------------------------------------------|----------------------------------------|--------------------------------------------|-------------------------------------|------------------------------------|----------------------------------------|--|-----------------------------------|-------------------------------------|----------------------------------|--------------------------------|--------------------------|--------------------------------------------|------------------------------------|-----------------------------------|----------------------------------|-------------------------------------|--|----------------------------------------|-------------------------------------|-----------------------------------|--------------------------------|----------------------------------------|-----------------------------|---------------------------------------|-------------------------------------|--|--|--|------------------------------|-------------------------------------------|-----------------------------------------------|--|--|--|------------------------------|-----------------------------------------|----------------------------------------------------|---------------------------------------------------|--|--|--------------------------------------------|--------------------------------|---------------------------------------------------|-----------------------------------------------------------|--|--|
| <b>Decision #:</b> 449308                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                            | <b>Registration #:</b> 100-RURR                    |                                                           |                                        |                                            |                                     |                                    |                                        |  |                                   |                                     |                                  |                                |                          |                                            |                                    |                                   |                                  |                                     |  |                                        |                                     |                                   |                                |                                        |                             |                                       |                                     |  |  |  |                              |                                           |                                               |  |  |  |                              |                                         |                                                    |                                                   |  |  |                                            |                                |                                                   |                                                           |  |  |
| <b>Petition #:</b> ---                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                            |                                                    |                                                           |                                        |                                            |                                     |                                    |                                        |  |                                   |                                     |                                  |                                |                          |                                            |                                    |                                   |                                  |                                     |  |                                        |                                     |                                   |                                |                                        |                             |                                       |                                     |  |  |  |                              |                                           |                                               |  |  |  |                              |                                         |                                                    |                                                   |  |  |                                            |                                |                                                   |                                                           |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                            |                                                    |                                                           |                                        |                                            |                                     |                                    |                                        |  |                                   |                                     |                                  |                                |                          |                                            |                                    |                                   |                                  |                                     |  |                                        |                                     |                                   |                                |                                        |                             |                                       |                                     |  |  |  |                              |                                           |                                               |  |  |  |                              |                                         |                                                    |                                                   |  |  |                                            |                                |                                                   |                                                           |  |  |
| <input type="checkbox"/> See page 2 for additional registration entries                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                            |                                                    |                                                           |                                        |                                            |                                     |                                    |                                        |  |                                   |                                     |                                  |                                |                          |                                            |                                    |                                   |                                  |                                     |  |                                        |                                     |                                   |                                |                                        |                             |                                       |                                     |  |  |  |                              |                                           |                                               |  |  |  |                              |                                         |                                                    |                                                   |  |  |                                            |                                |                                                   |                                                           |  |  |
| <b>Chemical Name:</b> emamectin benzoate                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                            |                                                    |                                                           |                                        |                                            |                                     |                                    |                                        |  |                                   |                                     |                                  |                                |                          |                                            |                                    |                                   |                                  |                                     |  |                                        |                                     |                                   |                                |                                        |                             |                                       |                                     |  |  |  |                              |                                           |                                               |  |  |  |                              |                                         |                                                    |                                                   |  |  |                                            |                                |                                                   |                                                           |  |  |
| <b>Fee Category:</b> R230                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                            | <b>PRIA Decision Time Frame:</b> 15 months         |                                                           |                                        |                                            |                                     |                                    |                                        |  |                                   |                                     |                                  |                                |                          |                                            |                                    |                                   |                                  |                                     |  |                                        |                                     |                                   |                                |                                        |                             |                                       |                                     |  |  |  |                              |                                           |                                               |  |  |  |                              |                                         |                                                    |                                                   |  |  |                                            |                                |                                                   |                                                           |  |  |
| <b>Submitted by:</b> Thomas                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                            | <b>Branch:</b> OCSPP/OPP/RD                        |                                                           |                                        |                                            |                                     |                                    |                                        |  |                                   |                                     |                                  |                                |                          |                                            |                                    |                                   |                                  |                                     |  |                                        |                                     |                                   |                                |                                        |                             |                                       |                                     |  |  |  |                              |                                           |                                               |  |  |  |                              |                                         |                                                    |                                                   |  |  |                                            |                                |                                                   |                                                           |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                            | <b>Date:</b> 08/08/2012                            |                                                           |                                        |                                            |                                     |                                    |                                        |  |                                   |                                     |                                  |                                |                          |                                            |                                    |                                   |                                  |                                     |  |                                        |                                     |                                   |                                |                                        |                             |                                       |                                     |  |  |  |                              |                                           |                                               |  |  |  |                              |                                         |                                                    |                                                   |  |  |                                            |                                |                                                   |                                                           |  |  |
| <b>Company:</b> Syngenta Crop Protection, LLC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                            |                                                    |                                                           |                                        |                                            |                                     |                                    |                                        |  |                                   |                                     |                                  |                                |                          |                                            |                                    |                                   |                                  |                                     |  |                                        |                                     |                                   |                                |                                        |                             |                                       |                                     |  |  |  |                              |                                           |                                               |  |  |  |                              |                                         |                                                    |                                                   |  |  |                                            |                                |                                                   |                                                           |  |  |
| <b>Original PRIA Due Date:</b> 09/08/2012                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                            | <b>Proposed New PRIA Due Date:</b> 10/25/2012      |                                                           |                                        |                                            |                                     |                                    |                                        |  |                                   |                                     |                                  |                                |                          |                                            |                                    |                                   |                                  |                                     |  |                                        |                                     |                                   |                                |                                        |                             |                                       |                                     |  |  |  |                              |                                           |                                               |  |  |  |                              |                                         |                                                    |                                                   |  |  |                                            |                                |                                                   |                                                           |  |  |
| <b>Previous Negotiated Due Dates:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                            |                                                    |                                                           |                                        |                                            |                                     |                                    |                                        |  |                                   |                                     |                                  |                                |                          |                                            |                                    |                                   |                                  |                                     |  |                                        |                                     |                                   |                                |                                        |                             |                                       |                                     |  |  |  |                              |                                           |                                               |  |  |  |                              |                                         |                                                    |                                                   |  |  |                                            |                                |                                                   |                                                           |  |  |
| <b>Is the "Fix" in-house?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> n/a <b>If not, date "Fix" expected:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                            |                                                    |                                                           |                                        |                                            |                                     |                                    |                                        |  |                                   |                                     |                                  |                                |                          |                                            |                                    |                                   |                                  |                                     |  |                                        |                                     |                                   |                                |                                        |                             |                                       |                                     |  |  |  |                              |                                           |                                               |  |  |  |                              |                                         |                                                    |                                                   |  |  |                                            |                                |                                                   |                                                           |  |  |
| <b>Negotiated Due Date Reason:</b><br><table style="width: 100%; border: none;"> <tr> <td style="width: 20%; vertical-align: top;"><b>Additional Data Required</b></td> <td style="width: 20%;"><input type="checkbox"/> Product Chemistry</td> <td style="width: 20%;"><input type="checkbox"/> Toxicology</td> <td style="width: 20%;"><input type="checkbox"/> Acute Tox</td> <td style="width: 20%;"><input type="checkbox"/> Environmental</td> </tr> <tr> <td></td> <td><input type="checkbox"/> Efficacy</td> <td><input type="checkbox"/> Ecological</td> <td><input type="checkbox"/> Residue</td> <td><input type="checkbox"/> Other</td> </tr> </table> <table style="width: 100%; border: none;"> <tr> <td style="width: 20%; vertical-align: top;"><b>Data Deficiencies</b></td> <td style="width: 20%;"><input type="checkbox"/> Product Chemistry</td> <td style="width: 20%;"><input type="checkbox"/> Acute Tox</td> <td style="width: 20%;"><input type="checkbox"/> Efficacy</td> <td style="width: 20%;"><input type="checkbox"/> Residue</td> <td style="width: 20%;"><input type="checkbox"/> Toxicology</td> </tr> <tr> <td></td> <td><input type="checkbox"/> Environmental</td> <td><input type="checkbox"/> Ecological</td> <td><input type="checkbox"/> Labeling</td> <td><input type="checkbox"/> Other</td> <td><input type="checkbox"/> Not Submitted</td> </tr> </table> <table style="width: 100%; border: none;"> <tr> <td style="width: 20%; vertical-align: top;"><b>Late Risk Assessment</b></td> <td style="width: 20%;"><input type="checkbox"/> Human Health</td> <td style="width: 20%;"><input type="checkbox"/> Ecological</td> <td colspan="3"></td> </tr> </table> <table style="width: 100%; border: none;"> <tr> <td style="width: 20%; vertical-align: top;"><b>Interim Consideration</b></td> <td style="width: 20%;"><input type="checkbox"/> Agency Initiated</td> <td style="width: 20%;"><input type="checkbox"/> Registrant Initiated</td> <td colspan="3"></td> </tr> </table> <table style="width: 100%; border: none;"> <tr> <td style="width: 20%;"><input type="checkbox"/> CSF</td> <td style="width: 20%;"><input type="checkbox"/> Public Process</td> <td style="width: 20%;"><input type="checkbox"/> Risk Issues Environmental</td> <td style="width: 20%;"><input type="checkbox"/> Risk Issues Human Health</td> <td colspan="2"></td> </tr> <tr> <td><input type="checkbox"/> Impurities Review</td> <td><input type="checkbox"/> Label</td> <td><input type="checkbox"/> Administrative-FR Notice</td> <td><input checked="" type="checkbox"/> Other – Comment Field</td> <td colspan="2"></td> </tr> </table> |                                            |                                                    |                                                           | <b>Additional Data Required</b>        | <input type="checkbox"/> Product Chemistry | <input type="checkbox"/> Toxicology | <input type="checkbox"/> Acute Tox | <input type="checkbox"/> Environmental |  | <input type="checkbox"/> Efficacy | <input type="checkbox"/> Ecological | <input type="checkbox"/> Residue | <input type="checkbox"/> Other | <b>Data Deficiencies</b> | <input type="checkbox"/> Product Chemistry | <input type="checkbox"/> Acute Tox | <input type="checkbox"/> Efficacy | <input type="checkbox"/> Residue | <input type="checkbox"/> Toxicology |  | <input type="checkbox"/> Environmental | <input type="checkbox"/> Ecological | <input type="checkbox"/> Labeling | <input type="checkbox"/> Other | <input type="checkbox"/> Not Submitted | <b>Late Risk Assessment</b> | <input type="checkbox"/> Human Health | <input type="checkbox"/> Ecological |  |  |  | <b>Interim Consideration</b> | <input type="checkbox"/> Agency Initiated | <input type="checkbox"/> Registrant Initiated |  |  |  | <input type="checkbox"/> CSF | <input type="checkbox"/> Public Process | <input type="checkbox"/> Risk Issues Environmental | <input type="checkbox"/> Risk Issues Human Health |  |  | <input type="checkbox"/> Impurities Review | <input type="checkbox"/> Label | <input type="checkbox"/> Administrative-FR Notice | <input checked="" type="checkbox"/> Other – Comment Field |  |  |
| <b>Additional Data Required</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <input type="checkbox"/> Product Chemistry | <input type="checkbox"/> Toxicology                | <input type="checkbox"/> Acute Tox                        | <input type="checkbox"/> Environmental |                                            |                                     |                                    |                                        |  |                                   |                                     |                                  |                                |                          |                                            |                                    |                                   |                                  |                                     |  |                                        |                                     |                                   |                                |                                        |                             |                                       |                                     |  |  |  |                              |                                           |                                               |  |  |  |                              |                                         |                                                    |                                                   |  |  |                                            |                                |                                                   |                                                           |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <input type="checkbox"/> Efficacy          | <input type="checkbox"/> Ecological                | <input type="checkbox"/> Residue                          | <input type="checkbox"/> Other         |                                            |                                     |                                    |                                        |  |                                   |                                     |                                  |                                |                          |                                            |                                    |                                   |                                  |                                     |  |                                        |                                     |                                   |                                |                                        |                             |                                       |                                     |  |  |  |                              |                                           |                                               |  |  |  |                              |                                         |                                                    |                                                   |  |  |                                            |                                |                                                   |                                                           |  |  |
| <b>Data Deficiencies</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <input type="checkbox"/> Product Chemistry | <input type="checkbox"/> Acute Tox                 | <input type="checkbox"/> Efficacy                         | <input type="checkbox"/> Residue       | <input type="checkbox"/> Toxicology        |                                     |                                    |                                        |  |                                   |                                     |                                  |                                |                          |                                            |                                    |                                   |                                  |                                     |  |                                        |                                     |                                   |                                |                                        |                             |                                       |                                     |  |  |  |                              |                                           |                                               |  |  |  |                              |                                         |                                                    |                                                   |  |  |                                            |                                |                                                   |                                                           |  |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <input type="checkbox"/> Environmental     | <input type="checkbox"/> Ecological                | <input type="checkbox"/> Labeling                         | <input type="checkbox"/> Other         | <input type="checkbox"/> Not Submitted     |                                     |                                    |                                        |  |                                   |                                     |                                  |                                |                          |                                            |                                    |                                   |                                  |                                     |  |                                        |                                     |                                   |                                |                                        |                             |                                       |                                     |  |  |  |                              |                                           |                                               |  |  |  |                              |                                         |                                                    |                                                   |  |  |                                            |                                |                                                   |                                                           |  |  |
| <b>Late Risk Assessment</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <input type="checkbox"/> Human Health      | <input type="checkbox"/> Ecological                |                                                           |                                        |                                            |                                     |                                    |                                        |  |                                   |                                     |                                  |                                |                          |                                            |                                    |                                   |                                  |                                     |  |                                        |                                     |                                   |                                |                                        |                             |                                       |                                     |  |  |  |                              |                                           |                                               |  |  |  |                              |                                         |                                                    |                                                   |  |  |                                            |                                |                                                   |                                                           |  |  |
| <b>Interim Consideration</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <input type="checkbox"/> Agency Initiated  | <input type="checkbox"/> Registrant Initiated      |                                                           |                                        |                                            |                                     |                                    |                                        |  |                                   |                                     |                                  |                                |                          |                                            |                                    |                                   |                                  |                                     |  |                                        |                                     |                                   |                                |                                        |                             |                                       |                                     |  |  |  |                              |                                           |                                               |  |  |  |                              |                                         |                                                    |                                                   |  |  |                                            |                                |                                                   |                                                           |  |  |
| <input type="checkbox"/> CSF                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <input type="checkbox"/> Public Process    | <input type="checkbox"/> Risk Issues Environmental | <input type="checkbox"/> Risk Issues Human Health         |                                        |                                            |                                     |                                    |                                        |  |                                   |                                     |                                  |                                |                          |                                            |                                    |                                   |                                  |                                     |  |                                        |                                     |                                   |                                |                                        |                             |                                       |                                     |  |  |  |                              |                                           |                                               |  |  |  |                              |                                         |                                                    |                                                   |  |  |                                            |                                |                                                   |                                                           |  |  |
| <input type="checkbox"/> Impurities Review                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <input type="checkbox"/> Label             | <input type="checkbox"/> Administrative-FR Notice  | <input checked="" type="checkbox"/> Other – Comment Field |                                        |                                            |                                     |                                    |                                        |  |                                   |                                     |                                  |                                |                          |                                            |                                    |                                   |                                  |                                     |  |                                        |                                     |                                   |                                |                                        |                             |                                       |                                     |  |  |  |                              |                                           |                                               |  |  |  |                              |                                         |                                                    |                                                   |  |  |                                            |                                |                                                   |                                                           |  |  |
| <b>Summary of Deficiency Type(s):</b> <input type="checkbox"/> Not Submitted (N) <input type="checkbox"/> Deficiencies (D)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                            |                                                    |                                                           |                                        |                                            |                                     |                                    |                                        |  |                                   |                                     |                                  |                                |                          |                                            |                                    |                                   |                                  |                                     |  |                                        |                                     |                                   |                                |                                        |                             |                                       |                                     |  |  |  |                              |                                           |                                               |  |  |  |                              |                                         |                                                    |                                                   |  |  |                                            |                                |                                                   |                                                           |  |  |
| <b>Product Chemistry:</b> <input type="checkbox"/> <b>Acute Tox:</b> <input type="checkbox"/> <b>Efficacy:</b> <input type="checkbox"/> <b>Labeling:</b> <input type="checkbox"/> <b>Ecological Data:</b> <input type="checkbox"/> <b>Other (describe):</b> <input type="checkbox"/>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                            |                                                    |                                                           |                                        |                                            |                                     |                                    |                                        |  |                                   |                                     |                                  |                                |                          |                                            |                                    |                                   |                                  |                                     |  |                                        |                                     |                                   |                                |                                        |                             |                                       |                                     |  |  |  |                              |                                           |                                               |  |  |  |                              |                                         |                                                    |                                                   |  |  |                                            |                                |                                                   |                                                           |  |  |
| <b>Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):</b><br>Phone discussions and email. Copy of Syngenta 8/8/12 email stating concurrence is attached (.pdf).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                            |                                                    |                                                           |                                        |                                            |                                     |                                    |                                        |  |                                   |                                     |                                  |                                |                          |                                            |                                    |                                   |                                  |                                     |  |                                        |                                     |                                   |                                |                                        |                             |                                       |                                     |  |  |  |                              |                                           |                                               |  |  |  |                              |                                         |                                                    |                                                   |  |  |                                            |                                |                                                   |                                                           |  |  |
| <b>"75 Day" Letter sent?</b> <input type="checkbox"/> Yes, Date sent <input checked="" type="checkbox"/> No and reason for none? <i>Add comments on page 2</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                            |                                                    |                                                           |                                        |                                            |                                     |                                    |                                        |  |                                   |                                     |                                  |                                |                          |                                            |                                    |                                   |                                  |                                     |  |                                        |                                     |                                   |                                |                                        |                             |                                       |                                     |  |  |  |                              |                                           |                                               |  |  |  |                              |                                         |                                                    |                                                   |  |  |                                            |                                |                                                   |                                                           |  |  |
| <b>Rationale for Proposed Due Date:</b> synchronize with cucurbit new use since analyses being done together                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                            |                                                    |                                                           |                                        |                                            |                                     |                                    |                                        |  |                                   |                                     |                                  |                                |                          |                                            |                                    |                                   |                                  |                                     |  |                                        |                                     |                                   |                                |                                        |                             |                                       |                                     |  |  |  |                              |                                           |                                               |  |  |  |                              |                                         |                                                    |                                                   |  |  |                                            |                                |                                                   |                                                           |  |  |
| <b>Registrant notified that this is the last negotiation?</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not Applicable                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                            |                                                    |                                                           |                                        |                                            |                                     |                                    |                                        |  |                                   |                                     |                                  |                                |                          |                                            |                                    |                                   |                                  |                                     |  |                                        |                                     |                                   |                                |                                        |                             |                                       |                                     |  |  |  |                              |                                           |                                               |  |  |  |                              |                                         |                                                    |                                                   |  |  |                                            |                                |                                                   |                                                           |  |  |
| <b>Approve:</b> <input checked="" type="checkbox"/>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                            | <b>Disapprove:</b> <input type="checkbox"/>        |                                                           |                                        |                                            |                                     |                                    |                                        |  |                                   |                                     |                                  |                                |                          |                                            |                                    |                                   |                                  |                                     |  |                                        |                                     |                                   |                                |                                        |                             |                                       |                                     |  |  |  |                              |                                           |                                               |  |  |  |                              |                                         |                                                    |                                                   |  |  |                                            |                                |                                                   |                                                           |  |  |
| <b>If disapproved, action to be taken:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                            |                                                    |                                                           |                                        |                                            |                                     |                                    |                                        |  |                                   |                                     |                                  |                                |                          |                                            |                                    |                                   |                                  |                                     |  |                                        |                                     |                                   |                                |                                        |                             |                                       |                                     |  |  |  |                              |                                           |                                               |  |  |  |                              |                                         |                                                    |                                                   |  |  |                                            |                                |                                                   |                                                           |  |  |
| <b>OD or DOD Signature:</b> CN=Marty Monell/OU=DC/O=USEPA/C=US                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                            |                                                    | <b>Date:</b> 08/20/2012                                   |                                        |                                            |                                     |                                    |                                        |  |                                   |                                     |                                  |                                |                          |                                            |                                    |                                   |                                  |                                     |  |                                        |                                     |                                   |                                |                                        |                             |                                       |                                     |  |  |  |                              |                                           |                                               |  |  |  |                              |                                         |                                                    |                                                   |  |  |                                            |                                |                                                   |                                                           |  |  |



|                           |                                 |                        |
|---------------------------|---------------------------------|------------------------|
| <b>Decision #:</b> 449308 | <b>Registration #:</b> 100-RURR | <b>Petition #:</b> --- |
|                           |                                 |                        |
|                           |                                 |                        |

**Issue(s) (describe in detail):**

Two new uses for emamectin benzoate were submitted close together: use on ornamentals submitted by Syngenta on 5/17/11, use on cucurbits (crop group 9) submitted by IR4 on 7/13/11. While tracked separately in OPPIN, the science reviews, analyses, and memos by HED and EFED are being done together. Negotiating the earlier PRIA due date (ornamentals) to synchronize with the later PRIA due date (cucurbits).

**Comment(s):**



**RE: synchronize PRIA due dates for emamectin ornamentals and cucurbits**

**tom.parshley** to: Thomas Harris

08/08/2012 02:31 PM

**Cc:** carolyn.brinkley, data.mgmt, pat.eay

**From:** <tom.parshley@syngenta.com>

**To:** Thomas Harris/DC/USEPA/US@EPA

**Cc:** <carolyn.brinkley@syngenta.com>, <data.mgmt@syngenta.com>, <pat.eay@syngenta.com>

**History:** This message has been replied to.

Tom: Syngenta agrees to the revised PRIA date of October 25, 2012 for a registration decision on 100-RURR (includes new ornamental use) that coincides with the PRIA action for the addition of crop group 9 (cucurbits) for 100-1270 and 100-904.

Best regards,  
Tom

**From:** Thomas Harris [mailto:harris.thomas@epamail.epa.gov]

**Sent:** Tuesday, August 07, 2012 5:14 PM

**To:** Parshley Tom USGR

**Subject:** Fw: synchronize PRIA due dates for emamectin ornamentals and cucurbits

Tom,

Following on discussions on this topic, just send me an email back to this message that you agree with the proposal to synchronize the emamectin PRIA due dates for cucurbits and ornamentals to the 10/25/12 cucurbits date. I can then take care of the negotiated due date at my end..Thanks.

Tom Harris

EPA/OPPTS/OPP/RD/IRB

voice: (703) 308-9423

fax: (703) 308-0029

harris.thomas@epa.gov

visit <http://www.epa.gov/pesticides>

----- Forwarded by Thomas Harris/DC/USEPA/US on 08/07/2012 05:12 PM -----

**From:** Thomas Harris/DC/USEPA/US

**To:** tom.parshley@syngenta.com

**Cc:** carolyn.brinkley@syngenta.com

**Date:** 07/26/2012 06:33 PM

**Subject:** synchronize PRIA due dates for emamectin ornamentals and cucurbits

Tom,

Carolyn may have mentioned this to you already. We have pending applications for emamectin on both ornamentals (100-RURR) and cucurbits, crop group 9 (100-1270, 100-904). These applications came in a slightly different times but are being worked on together by our science divisions with the overlapping reviews (exposure, environmental fate, ecological effects) being written up in the same memos.

Since the analyses are being combined I would like to synchronize the PRIA due dates. Right now the ornamentals are due 9/8/12 and the cucurbits are due 10/25/12. Would you agree to negotiating the due date for the ornamentals to match the cucurbits, i.e. 10/25/12?

Just send me a response to this email and I can take care of the paperwork at this end. If you would like to talk about this give me a call on Tues 7/31 (I'll be out until then).

Thanks.

Tom Harris  
EPA/OPPTS/OPP/RD/IRB  
voice: (703) 308-9423  
fax: (703) 308-0029  
harris.thomas@epa.gov  
visit <http://www.epa.gov/pesticides>

This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.



# Audit Trail for

## Recommendation of Division Directors Negotiated Due Dates

**PDF Name:** PRIAv4a.pdf

**Form Number:** PRIA

**Document Identifier:** PRIA-12221152200-TH

SUBMITTED on 08/08/2012 at 03:40:12 PM by CN=Thomas Harris/OU=DC/O=USEPA/C=US

APPROVED on 08/08/2012 at 05:06:27 PM by CN=Meredith Laws/OU=DC/O=USEPA/C=US

APPROVED on 08/10/2012 at 10:37:34 AM by CN=Dan Rosenblatt/OU=DC/O=USEPA/C=US

APPROVED AND COMPLETED on 08/20/2012 at 07:52:44 AM by CN=Marty Monell/OU=DC/O=USEPA/C=US

## Harris, Thomas

---

**From:** tom.parshley@syngenta.com  
**Sent:** Tuesday, April 30, 2013 10:06 AM  
**To:** Harris, Thomas  
**Cc:** data.mgmt@syngenta.com; pat.eay@syngenta.com  
**Subject:** FW: emamectin ornamentals - quick label changes  
**Attachments:** 000100-XRURR.20120430.ENFOLD\_NEW\_F\_APR2013-HILITE.pdf; 000100-XRURR.20120430.ENFOLD\_NEW\_F\_APR2013-CLEAN.pdf

Tom: Here is the revised labeling as requested. Thanks for bringing the additional changes to our attention.

Best regards,  
Tom

---

**From:** Laird Patsy USGR  
**Sent:** Tuesday, April 30, 2013 9:56 AM  
**To:** Parshley Tom USGR  
**Subject:** RE: emamectin ornamentals - quick label changes

DONE

---

**From:** Parshley Tom USGR  
**Sent:** Tuesday, April 30, 2013 8:47 AM  
**To:** Laird Patsy USGR  
**Subject:** FW: emamectin ornamentals - quick label changes

Patsy: Please see two more changes on the Enfold label EPA is requesting. Thanks for doing this today if possible.

Tom

---

**From:** Harris, Thomas [<mailto:harris.thomas@epa.gov>]  
**Sent:** Monday, April 29, 2013 6:19 PM  
**To:** Parshley Tom USGR  
**Subject:** emamectin ornamentals - quick label changes

Tom,

Thanks for the quick turnaround on the revised Enfold labels. They look fine with just a couple of minor additions:

- P 9 – Application Prohibitions: ADD a bullet (second would be good) that says “Open cab airblast application is prohibited; airblast applications must use an enclosed cab.” [or similar] [sorry, I should have thought of this before]
- 
- P. 20 – Container label, Precautionary Statements: In the last email I requested that you repeat the new Environmental Hazards section here. However, you only included the bee paragraph. Please include the full header and both text paragraphs as on the full label.

Tom Harris  
EPA/OCSPP/OPP/RD

voice: (703) 308-9423  
fax: (703) 308-0029  
[harris.thomas@epa.gov](mailto:harris.thomas@epa.gov)

---

*This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.*



(Booklet)

**RESTRICTED USE PESTICIDE**

**TOXIC TO FISH, MAMMALS, AND AQUATIC ORGANISMS**

FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION.

**Enfold™**

Insecticide

**GROUP 6 INSECTICIDE**

For control of listed lepidopterous larvae (worms/caterpillars) and suppression of leafminers and spider mites on outdoor-grown plants in commercial nursery production

Active Ingredient:

Emamectin benzoate (CAS No. 155569-91-8) .....5.0%

Other Ingredients: .....95.0%

Total: .....100.0%

Enfold is a soluble granule containing 5% emamectin benzoate.

**KEEP OUT OF REACH OF CHILDREN.**

**CAUTION**

See additional precautionary statements and directions for use in booklet.

EPA Reg. No. 100-XXXX

EPA Est. XXXXX

Product of XXXXX

Formulated in XXXXX

SCP

Net Weight

| <b>FIRST AID</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                            |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>If swallowed</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <ul style="list-style-type: none"> <li>• Call poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul> |
| <b>If in eyes</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>                                                    |
| <b>If on skin or clothing</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>                                                                                                                      |
| <b>If inhaled</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>                                                |
| <p align="center"><b>NOTE TO PHYSICIAN</b></p> <p>Early signs of intoxication include dilation of pupils, muscular incoordination, and muscular tremors. Vomiting within one-half hour of exposure can minimize toxicity following accidental ingestion of the product; rapidly after exposure (&lt; 15 minutes), administer repeatedly medical charcoal in a large quantity of water or ipecac.</p> <p>If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements.</p> <p>In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since emamectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic emamectin benzoate exposure.</p> <p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p> |                                                                                                                                                                                                                                                                                                                                                            |

**HOT LINE NUMBER**

For 24-Hour Medical Emergency Assistance (Human or Animal)  
Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident)

Call

**1-800-888-8372**

---

**PRECAUTIONARY STATEMENTS**

---

**Hazards to Humans and Domestic Animals**

**CAUTION**

Harmful if swallowed, inhaled, or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Avoid breathing dust or spray mist. Prolonged or frequently repeated exposure may cause allergic skin reactions in some individuals.

**Personal Protective Equipment (PPE)**

- **Ground and Handheld Application (except airblast sprayers):**

**Mixers, loaders, and other handlers must wear:**

- Long-sleeved shirt and long pants
- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber
- Shoes plus socks
- NIOSH-approved respirator with a dust-mist filter with MSAH/NIOSH approval number prefix TC-21 or any N, R, P, or HE filter.

**Applicators must wear:**

- Long-sleeved shirt and long pants
- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber
- Shoes plus socks

- **Airblast Application:**

**Mixers, loaders, and other handlers must wear:**

- Long-sleeved shirt and long pants
- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber



- Shoes plus socks
- NIOSH-approved respirator with a dust-mist filter with MSAH/NIOSH approval number prefix TC-21 or any N, R, P, or HE filter.

#### **Applicators using ENCLOSED CAB airblast sprayers**

##### **While inside the cab must wear:**

- Long-sleeved shirt and long pants
- Shoes plus socks

##### **When entering or leaving the cab must also wear:**

- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber.

**NOTE:** Once inside the cab, applicator must remove gloves and store them in a chemical-resistant container such as a plastic bag.

- **Aerial application:**

##### **Mixers, loaders, and other handlers must wear:**

- Coveralls over long-sleeved shirt and long pants
- Shoes plus socks
- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber
- Dust/Mist-filtering respirator or a NIOSH-approved respirator with any N, R, P, or HE filter

#### **Applicators (Enclosed Cockpit)**

##### **While inside the cockpit must wear:**

- Long-sleeved shirt and long pants
- Shoes plus socks

##### **When entering or leaving the cockpit must also wear:**

- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber.

**NOTE:** Once inside the cockpit, applicator must remove gloves and store them in a chemical-resistant container such as a plastic bag.

##### **Flaggers must wear:**

- Long-sleeved shirt and long pants
- Shoes plus socks
- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

### **Engineering Controls**

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170-240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

### **User Safety Recommendations**

#### **Users should:**

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothes immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

### **Environmental Hazards**

This pesticide is toxic to fish, birds, mammals, and aquatic invertebrates. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash water or rinsate.

This product is highly toxic to bees if exposed to direct treatment or residues on blooming crops or other plants for up to 24 hours after application. To reduce potential exposure to pollinators that may be visiting the treatment area, do not apply this product or allow drift to blooming, pollen-shedding, or nectar-producing parts of plants during this time period.

### **Physical or Chemical Hazards**

Do not use or store near heat or open flame.

---

## CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

---

**NOTICE:** Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, LLC or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions, or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and (2) Buyer and User assume the risk of any such use. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.**

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.



## DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Enfold must be used only in accordance with directions on this label or in separately published Syngenta supplemental labeling for this product.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber, or butyl rubber
- Shoes plus socks
- Protective eyewear

**FAILURE TO FOLLOW DIRECTIONS AND PRECAUTIONS ON THIS LABEL MAY RESULT IN POOR INSECT CONTROL.**

---

**GENERAL INFORMATION**

---

Enfold is a selective insecticide for use on herbaceous and woody ornamental plants grown outdoors (in containers or in the ground) in commercial nursery production. Woody ornamentals include (but are not limited to) shrubs, non-bearing fruit and nut trees, Christmas trees, forest seedlings, and shade trees.

Enfold controls the larval stages (worms/caterpillars) of listed lepidopteran species and suppresses Liriomyza leafminer, Tetranychid mites and pear psylla. Enfold has contact activity, but is most efficacious when ingested by the pest. Shortly after exposure to Enfold, affected larvae are paralyzed, stop feeding, and subsequently die after 2-4 days.

- Apply Enfold to plant foliage when larvae first appear (immediately after egg hatch), but before populations reach damaging levels. Target Enfold applications at small (1/4 inch in length) larvae.
- Treatments must be made before larvae penetrate plant parts or before larvae begin webbing and sheltering.
- Thorough spray coverage is essential for optimum performance. Apply Enfold in sufficient water to ensure good coverage of all plant surfaces. The use of greater water volumes will generally result in better coverage, especially under adverse conditions (e.g., hot, dry) or when the plant canopy is dense.

**Resistance Management**

Enfold is a Group 6 insecticide (contains the active ingredient emamectin benzoate).

Because of the inherent risks of resistance development to any product, it is strongly advised that Enfold be used in a sound resistance management program. Treatment may not be effective against labeled pests if tolerant strains of insects or mites develop. When applying Enfold to plants that are hosts of labeled pests and these labeled pests have multiple generations per crop per year, use resistance management practices.

**Resistance management practices** may include, but are not limited to:

- Rotating Enfold with other products with different modes of action
- Avoiding treatment of successive pest generations with Enfold
- Using labeled rates at the specified spray intervals
- Using non-chemical alternatives such as beneficial arthropods
- Rotating susceptible to non-susceptible plants
- Using various cultural practices

For additional information regarding the implementation of these or other resistance management practices, consult your local agricultural advisor or company representative.

---

## APPLICATION PROCEDURES

---

### Application Prohibitions:

- **Chemigation:** Do not apply this product through any type of irrigation system.
- Open cab airblast application is prohibited; airblast applications must use an enclosed cab.
- **State Restriction:** Do not apply Enfold with aircraft in New York State.

### Spray Equipment

Apply by ground, airblast sprayer or aircraft. Spray equipment configuration should be arranged to provide accurate, uniform, and thorough coverage of the target crop and minimize potential for spray drift. Use spray nozzles that provide medium to fine-sized droplets. To ensure accuracy, calibrate sprayer before each use. For spray equipment and calibration information, consult sprayer manufacturers and/or state recommendations. All ground and aerial application equipment must be properly maintained and calibrated using appropriate carriers.

### Spray Volume

- Applications using sufficient water volume for thorough and uniform coverage of the target crop provide the most effective pest control.
- Avoid application when uniform coverage is not possible or if excessive spray drift or inversion is possible.

---

## SPRAY DRIFT

---

**NOTE:** When states have more stringent regulations, they must be observed.

### Spray Drift Precautions – Aircraft and Ground Application Equipment

Apply Enfold only when wind velocity favors on-target product deposition (approximately 3 to 10 mph).

- **Do not** apply with ground application equipment within 25 ft. of or with aircraft within 150 ft. of lakes, reservoirs, rivers, permanent streams, marshes, pot holes, natural ponds, estuaries, or commercial fish farm ponds.



- **Do not** cultivate within 25 ft. of the aquatic area to allow growth of a vegetative filter strip.
- **Do not** allow this product to drift onto non-target areas. Drift may result in illegal residues or injury to non-target species. Risk of exposure to sensitive areas can be reduced by applying this product when the wind direction is away from the sensitive area.
- **Do not** apply when the weather conditions may cause drift:
  - Avoid application when the temperature is high and/or the humidity is low. These conditions increase the evaporation of spray droplets and the likelihood of drift to aquatic areas.
  - **Do not** apply when wind speed or wind gusts are greater than 10 mph.
  - **Do not** apply when wind speed is below 2 mph because wind direction will vary and there is a high potential for inversion.

### **Spray Drift Precautions (Aerial Application)**

#### **Responsibility**

Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment- and weather-related factors determines the potential for spray drift. The applicator is responsible for considering all of these factors when making application decisions.

#### **Drift Management Requirements**

The following drift management requirements must be followed to avoid off-target movement from aerial applications to non-target plants.

- **Outermost Nozzle Distance**  
The distance of the outermost nozzles on the boom must not exceed  $\frac{3}{4}$  the length of the wingspan or rotor.
- **Nozzle Direction**  
Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees.
- **Maximum Wind Speed**  
Do not apply when wind speed is greater than 10 mph.
- **Droplet Size**  
The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential

but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions. (See **Wind, Temperature and Humidity**, and **Temperature Inversions** sections.)

- **Controlling Droplet Size**

- Volume**

- Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets.

- Pressure**

- Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types, lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure.

- Number of Nozzles**

- Use the minimum number of nozzles that provide uniform coverage.

- Nozzle Orientation**

- Orienting nozzles so that the spray is released parallel to the air stream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential.

- Nozzle Type**

- Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid-stream nozzles oriented straight back produce the largest droplets and the lowest drift.

- **Boom Length**

- For some use patterns, reducing the effective boom length to less than  $\frac{3}{4}$  of the wingspan or rotor length may further reduce drift without reducing swath width.

- **Application Height**

- Applications should not be made at a height greater than 10 ft. above the top of the target plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind.

- **Swath Adjustment**

- When applications are made with a cross wind, the swath will be displaced downwind. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind.

- **Wind**

- Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any



given speed. Application must be avoided below 2 mph due to variable wind direction and high inversion potential. **NOTE:** Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift.

- **Temperature and Humidity**

To compensate for evaporation when applying Enfold in low relative humidity, set up equipment to produce larger droplets. Evaporation of droplets is most severe when conditions are both hot and dry.

- **Temperature Inversions**

Enfold must not be applied during a temperature inversion because the potential for drift is high. Temperature inversions restrict vertical air mixing, and this causes small, suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds that are common during inversions. Temperature inversions are characterized by temperatures that increase with altitude and are common on nights with limited cloud cover and light to no wind. Inversions begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, the movement of smoke from a ground source or an aircraft smoke generator can also identify inversions. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates, indicates good vertical air mixing.

---

## **MIXING PROCEDURES**

---

1. Thoroughly clean spray equipment before using this product.
2. Prepare no more spray mixture than is needed for the immediate application.
3. Keep product container tightly closed when not in use.
4. Agitate the spray solution before and during application.
5. Do not let the spray mixture stand overnight in the spray tank.
6. Flush the spray equipment thoroughly following each use and apply rinsate to a previously treated area.

### **Mixing Instructions: Enfold Alone**

1. Add 1/3 of the required amount of water to the spray or mixing tank.
2. With the agitator running, add Enfold into the spray tank.
3. Continue agitation while adding the remainder of the water.
4. Begin application of the solution after Enfold has completely dispersed into the mix water.
5. Maintain agitation until all of the mixture has been applied.

**Note:** Do not use liquid fertilizer as a carrier for Enfold.



## Enfold - Tank Mixtures

### Compatibility

Enfold is compatible with most insecticide, fungicide, and foliar nutrient products. However, before tank mixing Enfold use a jar test, as described below, to test the physical compatibility of Enfold with tank mix partners.

1. Using a quart jar, add the proportionate amounts of the products to 1 qt. of water. Add wettable powders and water-dispersible granular products first, then liquid flowables, and emulsifiable concentrates last.
2. After thoroughly mixing, let the mixture stand for at least 5 minutes. If the combination remains mixed or can be remixed readily, it is physically compatible.
3. If compatibility is acceptable, follow the instructions in **Mixing Instructions: Enfold Tank Mixtures**.

### NOTE:

- If using Enfold in a tank mixture:
  - Do not mix with any product that prohibits such mixing.
  - Observe all directions for use, crop/sites, use rates, dilution ratios, precautions, and limitations that appear on the tank mix product label.
  - Do not exceed any labeled use rate.
  - Follow the most restrictive label precautions and limitations.
- Tank mixtures or other applications of products referenced on this label are permitted only in those states in which the referenced products are labeled.

### Mixing Instructions: Enfold Tank Mixtures

1. Add 1/3 of the required amount of water to the mix tank.
2. Start the agitator running before adding any tank-mix partners.
3. When using Enfold in tank mixtures:
  - a. All products in water-soluble packaging should be added to the tank before any other tank-mix partner, including Enfold.
  - b. Allow the water-soluble packaging to completely dissolve and the product(s) to completely disperse before adding any other tank-mix partner to the tank.
  - c. Then add other tank-mix partners in this order: wettable powders, wettable granules (dry flowables), liquid flowables, liquids and emulsifiable concentrates. Always allow each tank mix partner to become fully dispersed before adding the next product.
4. Provide sufficient agitation while adding the remainder of the water.
5. Maintain agitation until all the mixture has been applied.

---

## USE DIRECTIONS

---

- **Location Prohibition:** Do not use Enfold in greenhouses.
- **Number of Applications:** Do not apply more than 3 sequential applications of Enfold. Rotate to another insect control product with a different mode of action for at least two applications.
- **Adjuvant Recommendation:** Thorough spray coverage of plant foliage is essential for optimum control. To provide optimum coverage and insect control, the use of a penetrating type spray adjuvant such as horticultural spray oil (not a dormant oil) or a nonionic surfactant at the manufacturer's suggested rate is recommended. Do not use a sticker/binder type adjuvant or tank mix with products that contain a sticker/binder component in the formulation because this may reduce Enfold insect control.
- **Application following failure of another insecticide:** Do not apply Enfold following the failure of another product if the larvae are large (>1/4 inch long).

### Plant Safety

**NOTICE TO USER:** Plant tolerance to Enfold has been found to be acceptable for many genera and species. Due to the large number of species and varieties of ornamentals and nursery plants, it is impossible to test every one for tolerance to Enfold. The professional user should determine if Enfold can be used safely prior to commercial use. In a small area, test the recommended rates on a small number of plants for phytotoxicity prior to widespread use.

**Tank Mixture:** The safety of all potential tank mixes on all plants may not have been tested. Before applying any tank mixture not specifically recommended on this label, the safety to the target plants should be confirmed.

| Pest                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | oz. Product/A per Application | Instructions                                                                                                                                                                                                    |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Beet armyworm<br>Cabbage looper<br>Cabbage webworm<br>Corn earworm<br>Cross-striped cabbageworm<br>Diamondback moth<br>Fall armyworm<br>Imported cabbageworm<br>Southern armyworm<br>Tobacco budworm<br>Tobacco hornworm<br>Tomato hornworm<br>Tomato fruitworm<br>Tomato pinworm<br>Yellowstriped armyworm                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 2.4-4.8 oz./A                 | Apply when larvae are first observed.<br>Application may be repeated at a 7- to 14-day interval to maintain control.<br><br>Use 2.4 oz./A for low to moderate infestations and 4.8 oz./A for high infestations. |
| Alfalfa looper<br>Apple pandemis<br>Bagworm<br>Bud moths:<br>eyespotted<br>tufted apple<br>Cabbage looper<br>Cankerworm species<br>Codling moth<br>Common winter moth<br>European winter moth<br>Fall webworm<br>Filbertworm<br>Fruitworms:<br>cherry<br>green species<br>laconobia<br>Genista caterpillar<br>Gypsy moth<br>Hickory shuckworm<br>Leafminers:<br>blister moth species<br>tentiform species<br>Leafrollers:<br>filbert<br>fruittree<br>obliquebanded<br>omnivorous<br>redbanded<br>variegated<br>Lesser appleworm<br>Liriomyza leafminers <sup>1</sup><br>Mimosa webworm<br>Navel orangeworm<br>Peach twig borer<br>Omnivorous leaf-tier<br>Orange tortrix<br>Oriental fruit moth<br>Pear psylla <sup>2</sup><br>Pecan bud moth<br>Pecan casebearer species | 3.2-4.8 oz./A                 | Apply when larvae are first observed.<br>Application may be repeated at a 7- to 14-day interval to maintain control.<br><br>Use 3.2 oz./A for low to moderate infestations and 4.8 oz./A for high infestations. |



|                             |  |  |
|-----------------------------|--|--|
| Pecan serpentine leafminer  |  |  |
| Redhumped caterpillar       |  |  |
| Soybean looper              |  |  |
| Spider mites <sup>2,3</sup> |  |  |
| Spruce budworm              |  |  |
| Tent Caterpillars:          |  |  |
| Eastern                     |  |  |
| Forest                      |  |  |
| Walnut caterpillar          |  |  |

- <sup>1</sup> Enfold provides suppression of *Liriomyza trifolii*, *Liriomyza sativae*, and *Liriomyza hudriobrensis* populations. Suppression means either erratic control ranging from good to poor or consistent control at a level below that which is generally considered acceptable for commercial control.
- <sup>2</sup> Enfold provides suppression. Suppression means either erratic control ranging from good to poor or consistent control at a level below that which is generally considered acceptable for commercial control.
- <sup>3</sup> Refers to phytophagous mites in the Acari subfamily Tetranychinae.

### Enfold Mixing Aid and Spray Volume Dilution Chart

Ounces of Enfold Added to Specified Spray Solution Mix Volumes Based on Listed Product Application Rate and Application Volume

| Application Volume<br>(Gallons Per Acre) | Application Rate<br>(Ounces of Product<br>Per Acre) | 25 Gallons of<br>Finished Spray | 50 Gallons of<br>Finished<br>Spray | 100 Gallons of<br>Finished<br>Spray |
|------------------------------------------|-----------------------------------------------------|---------------------------------|------------------------------------|-------------------------------------|
| 50                                       | 2.4                                                 | 1.2                             | 2.4                                | 4.8                                 |
| 50                                       | 3.2                                                 | 1.6                             | 3.2                                | 6.4                                 |
| 50                                       | 4.8                                                 | 2.4                             | 4.8                                | 9.6                                 |
| 100                                      | 2.4                                                 | 0.6                             | 1.2                                | 2.4                                 |
| 100                                      | 3.2                                                 | 0.8                             | 1.6                                | 3.2                                 |
| 100                                      | 4.8                                                 | 1.2                             | 2.4                                | 4.8                                 |
| 150                                      | 2.4                                                 | 0.4                             | 0.8                                | 1.6                                 |
| 150                                      | 3.2                                                 | 0.53                            | 1.06                               | 2.1                                 |
| 150                                      | 4.8                                                 | 0.8                             | 1.6                                | 3.2                                 |
| 200                                      | 2.4                                                 | 0.3                             | 0.6                                | 1.2                                 |
| 200                                      | 3.2                                                 | 0.4                             | 0.8                                | 1.6                                 |
| 200                                      | 4.8                                                 | 0.6                             | 1.2                                | 2.4                                 |
| 250                                      | 2.4                                                 | 0.24                            | 0.48                               | 0.96                                |
| 250                                      | 3.2                                                 | 0.32                            | 0.64                               | 1.28                                |
| 250                                      | 4.8                                                 | 0.48                            | 0.96                               | 1.92                                |
| 300                                      | 2.4                                                 | 0.2                             | 0.4                                | 0.8                                 |
| 300                                      | 3.2                                                 | 0.26                            | 0.53                               | 1.06                                |
| 300                                      | 4.8                                                 | 0.4                             | 0.8                                | 1.6                                 |

1 ounce of Enfold = 9.5 teaspoons

Do not use household measuring utensils to measure Enfold.

### **Use Restrictions**

- Allow a minimum of 7 days between applications.
- Do not apply more than 28.8 oz./A per year.

---

## **STORAGE AND DISPOSAL**

---

Do not contaminate water, food, or feed by storage and disposal.

### **Pesticide Storage**

Store in a cool, dry area under lock and key. Post as a pesticide storage area. Always store pesticides in the original container. Store away from food, pet food, feed, seed, fertilizers, and veterinary supplies. Place liquid formulations on lower shelves and dry formulations above.

### **Pesticide Disposal**

Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

### **Container Handling**

Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration.

---

Enfold™, the ALLIANCE FRAME, the SYNGENTA Logo and the PURPOSE ICON are Trademarks of a Syngenta Group Company

©2012 Syngenta

For non-emergency (e.g., current product information) call  
Syngenta Crop Protection at 1-800-334-9481.

Manufactured for:  
Syngenta Crop Protection, LLC  
P.O. Box 18300  
Greensboro, North Carolina 27419-8300

SCP



(Non-detachable Container Label)

**RESTRICTED USE PESTICIDE**

**TOXIC TO FISH, MAMMALS, AND AQUATIC ORGANISMS**

FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION.

**Enfold™**

Insecticide

**GROUP 6 INSECTICIDE**

For control of listed lepidopterous larvae (worms/caterpillars) and suppression of leafminers and spider mites on outdoor-grown plants in commercial nursery production

Active Ingredient:

Emamectin benzoate (CAS No. 155569-91-8) .....5.0%

Other Ingredients: .....95.0%

Total: .....100.0%

Enfold Insecticide is a soluble granule containing 5% emamectin benzoate.

**KEEP OUT OF REACH OF CHILDREN.**

**CAUTION**

See additional precautionary statements and directions for use in booklet.

**AGRICULTURAL USE REQUIREMENTS**

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. Refer to supplemental labeling under "Agricultural Use Requirements" in the Directions for Use section for information about this standard.

EPA Reg. No. 100-XXXX

EPA Est. XXXXX

Product of XXXXX

Formulated in XXXXX

SCP

Net Weight

Refer to **FIRST AID** section in attached booklet for additional precautionary statements.

## **PRECAUTIONARY STATEMENTS**

### **Hazards to Humans and Domestic Animals**

#### **CAUTION**

Harmful if swallowed, inhaled, or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Avoid breathing dust or spray mist. Prolonged or frequently repeated exposure may cause allergic skin reactions in some individuals.

### **Environmental Hazards**

This pesticide is toxic to fish, birds, mammals, and aquatic invertebrates. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash water or rinsate.

This product is highly toxic to bees if exposed to direct treatment or residues on blooming crops or other plants for up to 24 hours after application. To reduce potential exposure to pollinators that may be visiting the treatment area, do not apply this product or allow drift to blooming, pollen-shedding, or nectar-producing parts of plants during this period.

### **Physical or Chemical Hazards**

Do not use or store near heat or open flame.

## **STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage and disposal.

### **Pesticide Storage**

Store in a cool, dry area under lock and key. Post as a pesticide storage area. Always store pesticides in the original container. Store away from food, pet food, feed, seed, fertilizers, and veterinary supplies. Place liquid formulations on lower shelves and dry formulations above.

## Pesticide Disposal

Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

## Container Handling

Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration.

**Chemigation: Do not apply this product through any type of irrigation system.**

---

Enfold™ and the SYNGENTA Logo are Trademarks of a Syngenta Group Company.

©2013 Syngenta

Manufactured for:  
Syngenta Crop Protection, LLC  
P.O. Box 18300  
Greensboro, North Carolina 27419-8300

## SCP

Enfold (draft new product) – pl – 5/13/11  
000100-XXXXX.20110516.ENFOLD\_NEW-PRODUCT\_MAY2011.pdf  
Enfold (draft new product-version b) CLEAN – pl – 9/21/11  
000100-XXXXX.20110921.ENFOLD\_NEW-PRODUCT-B\_SEP2011.pdf  
Enfold (draft new product-c) CLEAN – pl – 3/22/12  
000100-XXXXX.20120322.ENFOLD\_NEW\_C\_MAR2012.pdf  
Enfold (draft new product-d) CLEAN – pl – 3/27/12  
000100-XXXXX.20120327.ENFOLD\_NEW\_D\_MAR2012.pdf  
Enfold (draft new product-e) –HILITE – pl – 4/25/13  
000100-XRURR.20130425.ENFOLD\_NEW\_E\_APR2013-HILITE.pdf  
Enfold (draft new product-e) –CLEAN – pl – 4/25/13  
000100-XRURR.20130425.ENFOLD\_NEW\_E\_APR2013-CLEAN.pdf  
Enfold (draft new product-f) – HILITE – pl – 4/30/13  
000100-XRURR.20130430.ENFOLD\_NEW\_F\_APR2013-HILITE.pdf  
Enfold (draft new product-f) – CLEAN – pl – 4/30/13  
000100-XRURR.20130430.ENFOLD\_NEW\_F\_APR2013-CLEAN.pdf



## Harris, Thomas

---

**From:** Harris, Thomas  
**Sent:** Monday, April 29, 2013 6:19 PM  
**To:** 'tom.parshley@syngenta.com'  
**Subject:** emamectin ornamentals - quick label changes

Tom,

Thanks for the quick turnaround on the revised Enfold labels. They look fine with just a couple of minor additions:

- P 9 – Application Prohibitions: ADD a bullet (second would be good) that says “Open cab airblast application is prohibited; airblast applications must use an enclosed cab.” [or similar] [sorry, I should have thought of this before]
- 
- P. 20 – Container label, Precautionary Statements: In the last email I requested that you repeat the new Environmental Hazards section here. However, you only included the bee paragraph. Please include the full header and both text paragraphs as on the full label.

Tom Harris  
EPA/OCSP/OPP/RD  
voice: (703) 308-9423  
fax: (703) 308-0029  
[harris.thomas@epa.gov](mailto:harris.thomas@epa.gov)

## Harris, Thomas

---

**From:** tom.parshley@syngenta.com  
**Sent:** Friday, April 26, 2013 4:11 PM  
**To:** Harris, Thomas  
**Cc:** data.mgmt@syngenta.com; pat.eay@syngenta.com; fred.pearson@syngenta.com; tammy.tyler@syngenta.com; john.abbott@syngenta.com  
**Subject:** FW: Revised Enfold labels  
**Attachments:** 000100-XRURR.20120425.ENFOLD\_NEW\_E\_APR2013-HILITE.pdf; 000100-XRURR.20120425.ENFOLD\_NEW\_E\_APR2013-CLEAN.pdf  
**Importance:** High

Tom: Attached are revised Enfold labels, clean and highlighted that reflect the science reviews and your changes to the labeling for this product. Thanks for working with us to address all the issues that were raised during the review of this product for ornamental use. Syngenta looks forward to bringing this action to closure.

Best regards,  
Tom

---

**From:** Laird Patsy USGR  
**Sent:** Thursday, April 25, 2013 10:35 AM  
**To:** Parshley Tom USGR  
**Cc:** Cox Ty Gene USGR  
**Subject:** Revised Enfold labels  
**Importance:** High

*Patsy Laird*  
Labeling Specialist / Product Labeling & Technology  
Regulatory Affairs  
Syngenta Crop Protection, LLC

---

This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.

(Booklet)

**RESTRICTED USE PESTICIDE**

**TOXIC TO FISH, MAMMALS, AND AQUATIC ORGANISMS**

FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION.

**Enfold™**

Insecticide

**GROUP 6 INSECTICIDE**

For control of listed lepidopterous larvae (worms/caterpillars) and suppression of leafminers and spider mites on outdoor-grown plants in commercial nursery production

Active Ingredient:

Emamectin benzoate (CAS No. 155569-91-8) .....5.0%

Other Ingredients: .....95.0%

Total: .....100.0%

Enfold is a soluble granule containing 5% emamectin benzoate.

**KEEP OUT OF REACH OF CHILDREN.**

**CAUTION**

See additional precautionary statements and directions for use in booklet.

EPA Reg. No. 100-XXXX

EPA Est. XXXXX

Product of XXXXX

Formulated in XXXXX

SCP

Net Weight

*Corrections needed on  
pages 1, 20*



| <b>FIRST AID</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                            |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>If swallowed</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <ul style="list-style-type: none"> <li>• Call poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul> |
| <b>If in eyes</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>                                                    |
| <b>If on skin or clothing</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>                                                                                                                      |
| <b>If inhaled</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>                                                |
| <p align="center"><b>NOTE TO PHYSICIAN</b></p> <p>Early signs of intoxication include dilation of pupils, muscular incoordination, and muscular tremors. Vomiting within one-half hour of exposure can minimize toxicity following accidental ingestion of the product; rapidly after exposure (&lt; 15 minutes), administer repeatedly medical charcoal in a large quantity of water or ipecac.</p> <p>If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements.</p> <p>In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since emamectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic emamectin benzoate exposure.</p> <p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p> |                                                                                                                                                                                                                                                                                                                                                            |

**HOT LINE NUMBER**

For 24-Hour Medical Emergency Assistance (Human or Animal)  
Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident)

Call

**1-800-888-8372**

---

**PRECAUTIONARY STATEMENTS**

---

**Hazards to Humans and Domestic Animals**

**CAUTION**

Harmful if swallowed, inhaled, or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Avoid breathing dust or spray mist. Prolonged or frequently repeated exposure may cause allergic skin reactions in some individuals.

**Personal Protective Equipment (PPE)**

• **Ground and Handheld Application (except airblast sprayers):**

**Mixers, loaders, and other handlers must wear:**

- Long-sleeved shirt and long pants
- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber
- Shoes plus socks
- NIOSH-approved respirator with a dust-mist filter with MSAH/NIOSH approval number prefix TC-21 or any N, R, P, or HE filter.

**Applicators must wear:**

- Long-sleeved shirt and long pants
- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber
- Shoes plus socks

• **Airblast Application:**

**Mixers, loaders, and other handlers must wear:**

- Long-sleeved shirt and long pants
- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber

- Shoes plus socks
- NIOSH-approved respirator with a dust-mist filter with MSAH/NIOSH approval number prefix TC-21 or any N, R, P, or HE filter.

#### **Applicators using ENCLOSED CAB airblast sprayers**

##### **While inside the cab must wear:**

- Long-sleeved shirt and long pants
- Shoes plus socks

##### **When entering or leaving the cab must also wear:**

- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber.

**NOTE:** Once inside the cab, applicator must remove gloves and store them in a chemical-resistant container such as a plastic bag.

- **Aerial application:**

##### **Mixers, loaders, and other handlers must wear:**

- Coveralls over long-sleeved shirt and long pants
- Shoes plus socks
- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber
- Dust/Mist-filtering respirator or a NIOSH-approved respirator with any N, R, P, or HE filter

#### **Applicators (Enclosed Cockpit)**

##### **While inside the cockpit must wear:**

- Long-sleeved shirt and long pants
- Shoes plus socks

##### **When entering or leaving the cockpit must also wear:**

- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber.

**NOTE:** Once inside the cockpit, applicator must remove gloves and store them in a chemical-resistant container such as a plastic bag.

##### **Flaggers must wear:**

- Long-sleeved shirt and long pants
- Shoes plus socks
- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber.



Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

### **Engineering Controls**

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170-240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

### **User Safety Recommendations**

#### **Users should:**

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothes immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

### **Environmental Hazards**

This pesticide is toxic to fish, birds, mammals, and aquatic invertebrates. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash water or rinsate.

This product is highly toxic to bees if exposed to direct treatment or residues on blooming crops or other plants for up to 24 hours after application. To reduce potential exposure to pollinators that may be visiting the treatment area, do not apply this product or allow drift to blooming, pollen-shedding, or nectar-producing parts of plants during this time period.

### **Physical or Chemical Hazards**

Do not use or store near heat or open flame.

---

## CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

---

**NOTICE:** Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, LLC or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions, or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and (2) Buyer and User assume the risk of any such use. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.**

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

## **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Enfold must be used only in accordance with directions on this label or in separately published Syngenta supplemental labeling for this product.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

### **AGRICULTURAL USE REQUIREMENTS**

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber, or butyl rubber
- Shoes plus socks
- Protective eyewear



**FAILURE TO FOLLOW DIRECTIONS AND PRECAUTIONS ON THIS LABEL MAY RESULT IN POOR INSECT CONTROL.**

---

**GENERAL INFORMATION**

---

Enfold is a selective insecticide for use on herbaceous and woody ornamental plants grown outdoors (in containers or in the ground) in commercial nursery production. Woody ornamentals include (but are not limited to) shrubs, non-bearing fruit and nut trees, Christmas trees, forest seedlings, and shade trees.

Enfold controls the larval stages (worms/caterpillars) of listed lepidopteran species and suppresses Liriomyza leafminer, Tetranychid mites and pear psylla. Enfold has contact activity, but is most efficacious when ingested by the pest. Shortly after exposure to Enfold, affected larvae are paralyzed, stop feeding, and subsequently die after 2-4 days.

- Apply Enfold to plant foliage when larvae first appear (immediately after egg hatch), but before populations reach damaging levels. Target Enfold applications at small (1/4 inch in length) larvae.
- Treatments must be made before larvae penetrate plant parts or before larvae begin webbing and sheltering.
- Thorough spray coverage is essential for optimum performance. Apply Enfold in sufficient water to ensure good coverage of all plant surfaces. The use of greater water volumes will generally result in better coverage, especially under adverse conditions (e.g., hot, dry) or when the plant canopy is dense.

**Resistance Management**

Enfold is a Group 6 insecticide (contains the active ingredient emamectin benzoate).

Because of the inherent risks of resistance development to any product, it is strongly advised that Enfold be used in a sound resistance management program. Treatment may not be effective against labeled pests if tolerant strains of insects or mites develop. When applying Enfold to plants that are hosts of labeled pests and these labeled pests have multiple generations per crop per year, use resistance management practices.

**Resistance management practices** may include, but are not limited to:

- Rotating Enfold with other products with different modes of action
- Avoiding treatment of successive pest generations with Enfold
- Using labeled rates at the specified spray intervals
- Using non-chemical alternatives such as beneficial arthropods
- Rotating susceptible to non-susceptible plants
- Using various cultural practices

For additional information regarding the implementation of these or other resistance management practices, consult your local agricultural advisor or company representative.

---

## APPLICATION PROCEDURES

---

### Application Prohibitions:

- **Chemigation:** Do not apply this product through any type of irrigation system.
- **State Restriction:** Do not apply Enfold with aircraft in New York State.

### Spray Equipment

Apply by ground, airblast sprayer or aircraft. Spray equipment configuration should be arranged to provide accurate, uniform, and thorough coverage of the target crop and minimize potential for spray drift. Use spray nozzles that provide medium to fine-sized droplets. To ensure accuracy, calibrate sprayer before each use. For spray equipment and calibration information, consult sprayer manufacturers and/or state recommendations. All ground and aerial application equipment must be properly maintained and calibrated using appropriate carriers.

*Airblast applicators must be in an enclosed cab; open cab airblast application is prohibited*

### Spray Volume

- Applications using sufficient water volume for thorough and uniform coverage of the target crop provide the most effective pest control.
- Avoid application when uniform coverage is not possible or if excessive spray drift or inversion is possible.

---

## SPRAY DRIFT

---

**NOTE:** When states have more stringent regulations, they must be observed.

### Spray Drift Precautions – Aircraft and Ground Application Equipment

Apply Enfold only when wind velocity favors on-target product deposition (approximately 3 to 10 mph).

- **Do not** apply with ground application equipment within 25 ft. of or with aircraft within 150 ft. of lakes, reservoirs, rivers, permanent streams, marshes, pot holes, natural ponds, estuaries, or commercial fish farm ponds.
- **Do not** cultivate within 25 ft. of the aquatic area to allow growth of a vegetative filter strip.



- **Do not** allow this product to drift onto non-target areas. Drift may result in illegal residues or injury to non-target species. Risk of exposure to sensitive areas can be reduced by applying this product when the wind direction is away from the sensitive area.
- **Do not** apply when the weather conditions may cause drift:
  - Avoid application when the temperature is high and/or the humidity is low. These conditions increase the evaporation of spray droplets and the likelihood of drift to aquatic areas.
  - **Do not** apply when wind speed or wind gusts are greater than 10 mph.
  - **Do not** apply when wind speed is below 2 mph because wind direction will vary and there is a high potential for inversion.

### **Spray Drift Precautions (Aerial Application)**

#### **Responsibility**

Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment- and weather-related factors determines the potential for spray drift. The applicator is responsible for considering all of these factors when making application decisions.

#### **Drift Management Requirements**

The following drift management requirements must be followed to avoid off-target movement from aerial applications to non-target plants.

- **Outermost Nozzle Distance**  
The distance of the outermost nozzles on the boom must not exceed  $\frac{3}{4}$  the length of the wingspan or rotor.
- **Nozzle Direction**  
Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees.
- **Maximum Wind Speed**  
Do not apply when wind speed is greater than 10 mph.
- **Droplet Size**  
The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential but will not prevent drift if applications are made improperly, or under unfavorable



environmental conditions. (See **Wind, Temperature and Humidity**, and **Temperature Inversions** sections.)

- **Controlling Droplet Size**

- Volume**

- Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets.

- Pressure**

- Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types, lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure.

- Number of Nozzles**

- Use the minimum number of nozzles that provide uniform coverage.

- Nozzle Orientation**

- Orienting nozzles so that the spray is released parallel to the air stream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential.

- Nozzle Type**

- Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid-stream nozzles oriented straight back produce the largest droplets and the lowest drift.

- **Boom Length**

- For some use patterns, reducing the effective boom length to less than  $\frac{3}{4}$  of the wingspan or rotor length may further reduce drift without reducing swath width.

- **Application Height**

- Applications should not be made at a height greater than 10 ft. above the top of the target plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind.

- **Swath Adjustment**

- When applications are made with a cross wind, the swath will be displaced downwind. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind.

- **Wind**

- Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application must be avoided below 2 mph due to variable wind

direction and high inversion potential. **NOTE:** Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift.

- **Temperature and Humidity**

To compensate for evaporation when applying Enfold in low relative humidity, set up equipment to produce larger droplets. Evaporation of droplets is most severe when conditions are both hot and dry.

- **Temperature Inversions**

Enfold must not be applied during a temperature inversion because the potential for drift is high. Temperature inversions restrict vertical air mixing, and this causes small, suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds that are common during inversions. Temperature inversions are characterized by temperatures that increase with altitude and are common on nights with limited cloud cover and light to no wind. Inversions begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, the movement of smoke from a ground source or an aircraft smoke generator can also identify inversions. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates, indicates good vertical air mixing.

---

## **MIXING PROCEDURES**

---

1. Thoroughly clean spray equipment before using this product.
2. Prepare no more spray mixture than is needed for the immediate application.
3. Keep product container tightly closed when not in use.
4. Agitate the spray solution before and during application.
5. Do not let the spray mixture stand overnight in the spray tank.
6. Flush the spray equipment thoroughly following each use and apply rinsate to a previously treated area.

### **Mixing Instructions: Enfold Alone**

1. Add 1/3 of the required amount of water to the spray or mixing tank.
2. With the agitator running, add Enfold into the spray tank.
3. Continue agitation while adding the remainder of the water.
4. Begin application of the solution after Enfold has completely dispersed into the mix water.
5. Maintain agitation until all of the mixture has been applied.

**Note:** Do not use liquid fertilizer as a carrier for Enfold.

## Enfold - Tank Mixtures

### Compatibility

Enfold is compatible with most insecticide, fungicide, and foliar nutrient products. However, before tank mixing Enfold use a jar test, as described below, to test the physical compatibility of Enfold with tank mix partners.

1. Using a quart jar, add the proportionate amounts of the products to 1 qt. of water. Add wettable powders and water-dispersible granular products first, then liquid flowables, and emulsifiable concentrates last.
2. After thoroughly mixing, let the mixture stand for at least 5 minutes. If the combination remains mixed or can be remixed readily, it is physically compatible.
3. If compatibility is acceptable, follow the instructions in **Mixing Instructions: Enfold Tank Mixtures**.

### NOTE:

- If using Enfold in a tank mixture:
  - Do not mix with any product that prohibits such mixing.
  - Observe all directions for use, crop/sites, use rates, dilution ratios, precautions, and limitations that appear on the tank mix product label.
  - Do not exceed any labeled use rate.
  - Follow the most restrictive label precautions and limitations.
- Tank mixtures or other applications of products referenced on this label are permitted only in those states in which the referenced products are labeled.

### Mixing Instructions: Enfold Tank Mixtures

1. Add 1/3 of the required amount of water to the mix tank.
2. Start the agitator running before adding any tank-mix partners.
3. When using Enfold in tank mixtures:
  - a. All products in water-soluble packaging should be added to the tank before any other tank-mix partner, including Enfold.
  - b. Allow the water-soluble packaging to completely dissolve and the product(s) to completely disperse before adding any other tank-mix partner to the tank.
  - c. Then add other tank-mix partners in this order: wettable powders, wettable granules (dry flowables), liquid flowables, liquids and emulsifiable concentrates. Always allow each tank mix partner to become fully dispersed before adding the next product.
4. Provide sufficient agitation while adding the remainder of the water.
5. Maintain agitation until all the mixture has been applied.



---

## USE DIRECTIONS

---

- **Location Prohibition:** Do not use Enfold in greenhouses.
- **Number of Applications:** Do not apply more than 3 sequential applications of Enfold. Rotate to another insect control product with a different mode of action for at least two applications.
- **Adjuvant Recommendation:** Thorough spray coverage of plant foliage is essential for optimum control. To provide optimum coverage and insect control, the use of a penetrating type spray adjuvant such as horticultural spray oil (not a dormant oil) or a nonionic surfactant at the manufacturer's suggested rate is recommended. Do not use a sticker/binder type adjuvant or tank mix with products that contain a sticker/binder component in the formulation because this may reduce Enfold insect control.
- **Application following failure of another insecticide:** Do not apply Enfold following the failure of another product if the larvae are large (>1/4 inch long).

### Plant Safety

**NOTICE TO USER:** Plant tolerance to Enfold has been found to be acceptable for many genera and species. Due to the large number of species and varieties of ornamentals and nursery plants, it is impossible to test every one for tolerance to Enfold. The professional user should determine if Enfold can be used safely prior to commercial use. In a small area, test the recommended rates on a small number of plants for phytotoxicity prior to widespread use.

**Tank Mixture:** The safety of all potential tank mixes on all plants may not have been tested. Before applying any tank mixture not specifically recommended on this label, the safety to the target plants should be confirmed.

| Pest                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | oz. Product/A per Application | Instructions                                                                                                                                                                                                    |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Beet armyworm<br>Cabbage looper<br>Cabbage webworm<br>Corn earworm<br>Cross-striped cabbageworm<br>Diamondback moth<br>Fall armyworm<br>Imported cabbageworm<br>Southern armyworm<br>Tobacco budworm<br>Tobacco hornworm<br>Tomato hornworm<br>Tomato fruitworm<br>Tomato pinworm<br>Yellowstriped armyworm                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 2.4-4.8 oz./A                 | Apply when larvae are first observed.<br>Application may be repeated at a 7- to 14-day interval to maintain control.<br><br>Use 2.4 oz./A for low to moderate infestations and 4.8 oz./A for high infestations. |
| Alfalfa looper<br>Apple pandemis<br>Bagworm<br>Bud moths:<br>eyespotted<br>tufted apple<br>Cabbage looper<br>Cankerworm species<br>Codling moth<br>Common winter moth<br>European winter moth<br>Fall webworm<br>Filbertworm<br>Fruitworms:<br>cherry<br>green species<br>laconobia<br>Genista caterpillar<br>Gypsy moth<br>Hickory shuckworm<br>Leafminers:<br>blister moth species<br>tentiform species<br>Leafrollers:<br>filbert<br>fruittree<br>obliquebanded<br>omnivorous<br>redbanded<br>variegated<br>Lesser appleworm<br>Liriomyza leafminers <sup>1</sup><br>Mimosa webworm<br>Navel orangeworm<br>Peach twig borer<br>Omnivorous leaf-tier<br>Orange tortrix<br>Oriental fruit moth<br>Pear psylla <sup>2</sup><br>Pecan bud moth<br>Pecan casebearer species | 3.2-4.8 oz./A                 | Apply when larvae are first observed.<br>Application may be repeated at a 7- to 14-day interval to maintain control.<br><br>Use 3.2 oz./A for low to moderate infestations and 4.8 oz./A for high infestations. |

|                             |  |  |
|-----------------------------|--|--|
| Pecan serpentine leafminer  |  |  |
| Redhumped caterpillar       |  |  |
| Soybean looper              |  |  |
| Spider mites <sup>2,3</sup> |  |  |
| Spruce budworm              |  |  |
| Tent Caterpillars:          |  |  |
| Eastern                     |  |  |
| Forest                      |  |  |
| Walnut caterpillar          |  |  |

- <sup>1</sup> Enfold provides suppression of *Liriomyza trifolii*, *Liriomyza sativae*, and *Liriomyza hudriobrensis* populations. Suppression means either erratic control ranging from good to poor or consistent control at a level below that which is generally considered acceptable for commercial control.
- <sup>2</sup> Enfold provides suppression. Suppression means either erratic control ranging from good to poor or consistent control at a level below that which is generally considered acceptable for commercial control.
- <sup>3</sup> Refers to phytophagous mites in the Acari subfamily Tetranychinae.

### Enfold Mixing Aid and Spray Volume Dilution Chart

Ounces of Enfold Added to Specified Spray Solution Mix Volumes Based on Listed Product Application Rate and Application Volume

| Application Volume<br>(Gallons Per Acre) | Application Rate<br>(Ounces of Product<br>Per Acre) | 25 Gallons of<br>Finished Spray | 50 Gallons of<br>Finished<br>Spray | 100 Gallons of<br>Finished<br>Spray |
|------------------------------------------|-----------------------------------------------------|---------------------------------|------------------------------------|-------------------------------------|
| 50                                       | 2.4                                                 | 1.2                             | 2.4                                | 4.8                                 |
| 50                                       | 3.2                                                 | 1.6                             | 3.2                                | 6.4                                 |
| 50                                       | 4.8                                                 | 2.4                             | 4.8                                | 9.6                                 |
| 100                                      | 2.4                                                 | 0.6                             | 1.2                                | 2.4                                 |
| 100                                      | 3.2                                                 | 0.8                             | 1.6                                | 3.2                                 |
| 100                                      | 4.8                                                 | 1.2                             | 2.4                                | 4.8                                 |
| 150                                      | 2.4                                                 | 0.4                             | 0.8                                | 1.6                                 |
| 150                                      | 3.2                                                 | 0.53                            | 1.06                               | 2.1                                 |
| 150                                      | 4.8                                                 | 0.8                             | 1.6                                | 3.2                                 |
| 200                                      | 2.4                                                 | 0.3                             | 0.6                                | 1.2                                 |
| 200                                      | 3.2                                                 | 0.4                             | 0.8                                | 1.6                                 |
| 200                                      | 4.8                                                 | 0.6                             | 1.2                                | 2.4                                 |
| 250                                      | 2.4                                                 | 0.24                            | 0.48                               | 0.96                                |
| 250                                      | 3.2                                                 | 0.32                            | 0.64                               | 1.28                                |
| 250                                      | 4.8                                                 | 0.48                            | 0.96                               | 1.92                                |
| 300                                      | 2.4                                                 | 0.2                             | 0.4                                | 0.8                                 |
| 300                                      | 3.2                                                 | 0.26                            | 0.53                               | 1.06                                |
| 300                                      | 4.8                                                 | 0.4                             | 0.8                                | 1.6                                 |



1 ounce of Enfold = 9.5 teaspoons

Do not use household measuring utensils to measure Enfold.

### **Use Restrictions**

- Allow a minimum of 7 days between applications.
- Do not apply more than 28.8 oz./A per year.

---

## **STORAGE AND DISPOSAL**

---

Do not contaminate water, food, or feed by storage and disposal.

### **Pesticide Storage**

Store in a cool, dry area under lock and key. Post as a pesticide storage area. Always store pesticides in the original container. Store away from food, pet food, feed, seed, fertilizers, and veterinary supplies. Place liquid formulations on lower shelves and dry formulations above.

### **Pesticide Disposal**

Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

### **Container Handling**

Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container  $\frac{1}{4}$  full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration.

---

Enfold™, the ALLIANCE FRAME, the SYNGENTA Logo and the PURPOSE ICON are Trademarks of a Syngenta Group Company

©2012 Syngenta

For non-emergency (e.g., current product information) call  
Syngenta Crop Protection at 1-800-334-9481.

Manufactured for:  
Syngenta Crop Protection, LLC  
P.O. Box 18300  
Greensboro, North Carolina 27419-8300

SCP

(Non-detachable Container Label)

**RESTRICTED USE PESTICIDE**

**TOXIC TO FISH, MAMMALS, AND AQUATIC ORGANISMS**

FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION.

**Enfold™**

**Insecticide**

**GROUP 6 INSECTICIDE**

For control of listed lepidopterous larvae (worms/caterpillars) and suppression of leafminers and spider mites on outdoor-grown plants in commercial nursery production

Active Ingredient:

Emamectin benzoate (CAS No. 155569-91-8) .....5.0%

Other Ingredients: .....95.0%

Total: .....100.0%

Enfold Insecticide is a soluble granule containing 5% emamectin benzoate.

**KEEP OUT OF REACH OF CHILDREN.**

**CAUTION**

See additional precautionary statements and directions for use in booklet.

**AGRICULTURAL USE REQUIREMENTS**

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. Refer to supplemental labeling under "Agricultural Use Requirements" in the Directions for Use section for information about this standard.

EPA Reg. No. 100-XXXX

EPA Est. XXXXX

Product of XXXXX

Formulated in XXXXX

SCP

Net Weight



Refer to **FIRST AID** section in attached booklet for additional precautionary statements.

## **PRECAUTIONARY STATEMENTS**

### **Hazards to Humans and Domestic Animals**

#### **CAUTION**

Harmful if swallowed, inhaled, or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Avoid breathing dust or spray mist. Prolonged or frequently repeated exposure may cause allergic skin reactions in some individuals.

*Environmental Hazards Toxic to fish, birds etc*

This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or other plants for up to 24 hours after application. To reduce potential exposure to pollinators that may be visiting the treatment area, do not apply this product or allow drift to blooming, pollen-shedding, or nectar-producing parts of plants during this period.

### **Physical or Chemical Hazards**

Do not use or store near heat or open flame.

## **STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage and disposal.

### **Pesticide Storage**

Store in a cool, dry area under lock and key. Post as a pesticide storage area. Always store pesticides in the original container. Store away from food, pet food, feed, seed, fertilizers, and veterinary supplies. Place liquid formulations on lower shelves and dry formulations above.

### **Pesticide Disposal**

Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

## Container Handling

Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container  $\frac{1}{4}$  full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration.

**Chemigation: Do not apply this product through any type of irrigation system.**

*SS*  
Enfold™ and the SYNGENTA Logo are Trademarks of a Syngenta Group Company.

©2012 Syngenta

Manufactured for:  
Syngenta Crop Protection, LLC  
P.O. Box 18300  
Greensboro, North Carolina 27419-8300

SCP

Enfold (draft new product) – pl – 5/13/11  
000100-XXXXX.20110516.ENFOLD\_NEW-PRODUCT\_MAY2011.pdf

Enfold (draft new product-version b) CLEAN – pl – 9/21/11  
000100-XXXXX.20110921.ENFOLD\_NEW-PRODUCT-B\_SEP2011.pdf

Enfold (draft new product-c) CLEAN – pl – 3/22/12  
000100-XXXXX.20120322.ENFOLD\_NEW\_C\_MAR2012.pdf

Enfold (draft new product-d) CLEAN – pl – 3/27/12  
000100-XXXXX.20120327.ENFOLD\_NEW\_D\_MAR2012.pdf

Enfold (draft new product-e) –HILITE – pl – 4/25/13  
000100-XRURR.20130425.ENFOLD\_NEW\_E\_APR2013-HILITE.pdf

Enfold (draft new product-e) –CLEAN – pl – 4/25/13  
000100-XRURR.20130425.ENFOLD\_NEW\_E\_APR2013-CLEAN.pdf

## Harris,Thomas

---

**From:** Harris,Thomas  
**Sent:** Wednesday, April 24, 2013 3:53 PM  
**To:** 'tammy.tyler@syngenta.com'; tom.parshley@syngenta.com; Charles.Levey@syngenta.com; john.abbott@syngenta.com  
**Subject:** emamectin ornamental label corrections  
**Attachments:** 000100-0RURR.20120327.ENFOLD\_NEW\_D\_MAR2012.EPA COMMENTS.pdf;  
000100-0RURR.20120327.ENFOLD\_NEW\_D\_MAR2012.EPA COMMENTS.print image.pdf

100-RURR

Hitting a bit of a snag here on just accepting the ornamental label with comments. While I work on that, here are the required changes. Go ahead and send me a revised label. After I read the HED review carefully I realized this wasn't as bad as I had been expecting. The respirator is just dust/mist type and only for mixer/loader, not for applicator. Aerial can stay on ornamentals even without water soluble packaging (needed for cucurbits). Biggest change was deleting open cab for airblast applicators. Also an edit on Environmental Hazards.

Just print the "print image" version to a color printer. Other version useful if you want to copy/paste.

Tom Harris  
EPA/OCSP/OPP/RD  
voice: (703) 308-9423  
fax: (703) 308-0029  
[harris.thomas@epa.gov](mailto:harris.thomas@epa.gov)



(Booklet)

**RESTRICTED USE PESTICIDE**  
**TOXIC TO FISH, MAMMALS, AND AQUATIC ORGANISMS**  
FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR  
DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S  
CERTIFICATION.

**Enfold™**

Insecticide

**GROUP 6 INSECTICIDE**

For control of listed lepidopterous larvae (worms/caterpillars) and suppression of  
leafminers and spider mites on outdoor-grown plants in commercial nursery production

|                                          |        |
|------------------------------------------|--------|
| Active Ingredient:                       |        |
| Emamectin benzoate (CAS No. 155569-91-8) | 5.0%   |
| Other Ingredients:                       | 95.0%  |
| Total:                                   | 100.0% |

Enfold is a soluble granule containing 5% emamectin benzoate.

**KEEP OUT OF REACH OF CHILDREN.**

**CAUTION**

See additional precautionary statements and directions for use in booklet.

EPA Reg. No. 100-XXXX

EPA Est. XXXXX

Product of XXXXX  
Formulated in XXXXX

SCP

Net Weight

## Summary of Comments on Microsoft Word - Enfold \_draft new product- d\_ 3-27-12 CLEAN

Page: 1

|                                                             |                            |
|-------------------------------------------------------------|----------------------------|
| Author: thar02                                              | Date: 4/23/2013 3:57:32 PM |
| 000100-0RURR.20120327.ENFOLD_NEW_D_MAR2012.EPA COMMENTS.pdf |                            |
| Author: thar02                                              | Date: 4/23/2013 3:56:51 PM |
| 000100-0RURR.20120327.ENFOLD_NEW_D_MAR2012.EPA COMMENTS.pdf |                            |
| Author: thar02                                              | Date: 4/23/2013 3:39:28 PM |
| 000100-0RURR.20120327.ENFOLD_NEW_D_MAR2012.pdf              |                            |

This page contains no comments

| FIRST AID                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                            |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>If swallowed</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <ul style="list-style-type: none"> <li>• Call poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul> |
| <b>If in eyes</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>                                                    |
| <b>If on skin or clothing</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>                                                                                                                      |
| <b>If inhaled</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>                                                |
| <p><b>NOTE TO PHYSICIAN</b></p> <p>Early signs of intoxication include dilation of pupils, muscular incoordination, and muscular tremors. Vomiting within one-half hour of exposure can minimize toxicity following accidental ingestion of the product; rapidly after exposure (&lt; 15 minutes), administer repeatedly medical charcoal in a large quantity of water or ipecac.</p> <p>If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements.</p> <p>In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since emamectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic emamectin benzoate exposure.</p> <p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p> |                                                                                                                                                                                                                                                                                                                                                            |

### HOT LINE NUMBER

For 24-Hour Medical Emergency Assistance (Human or Animal)  
Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident)  
Call  
**1-800-888-8372**

## PRECAUTIONARY STATEMENTS

### Hazards to Humans and Domestic Animals

#### CAUTION

Harmful if swallowed, inhaled, or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Avoid breathing dust or spray mist. Prolonged or frequently repeated exposure may cause allergic skin reactions in some individuals.

### Personal Protective Equipment (PPE)

#### • Ground Application (except airblast sprayers):

**Applicators, mixers, loaders, and other handlers must wear:**

- Long-sleeved shirt and long pants
- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber
- Shoes plus socks

#### • Airblast Application:

**Mixers, loaders, and other handlers must wear:**

- Long-sleeved shirt and long pants
- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber
- Shoes plus socks

**Applicators using OPEN CAB airblast sprayers must wear:**

- Coveralls over long-sleeved shirt and long pants
- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber
- Shoes plus socks

Page: 3

Author: them02 Subject: Inserted Text Date: 4/23/2013 4:27:32 PM  
REPLACE with:

"Ground and Handheld Application (except airblast sprayers):"

Author: them02 Subject: Cross-Out Date: 4/23/2013 4:24:25 PM  
DELETE

Author: them02 Subject: Rectangle Date: 4/24/2013 2:27:18 PM  
ADD to ground mixer/loader/handler:

"- NIOSH-approved respirator with a dust-mist filter with MSHA/NIOSH approval number prefix TC-21 or any N, R, P, or HE filter."

Author: them02 Subject: Rectangle Date: 4/23/2013 4:28:32 PM

ADD separate section for ground applicators; same as mixer except without respirator:

"Applicators must wear:  
• Long-sleeved shirt and long pants  
• Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber  
• Shoes plus socks"

Author: them02 Subject: Rectangle Date: 4/24/2013 2:27:34 PM  
ADD to airblast mixer/loader/handler:

"- NIOSH-approved respirator with a dust-mist filter with MSHA/NIOSH approval number prefix TC-21 or any N, R, P, or HE filter."

Author: them02 Subject: Cross-Out Date: 4/23/2013 4:20:36 PM

DELETE open cab airblast application



This page contains no comments

#### Applicators using ENCLOSED CAB airblast sprayers

##### While inside the cab must wear:

- Long-sleeved shirt and long pants
- Shoes plus socks

##### When entering or leaving the cab must also wear:

- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber.

**NOTE:** Once inside the cab, applicator must remove gloves and store them in a chemical-resistant container such as a plastic bag.

#### • Aerial application:

##### Mixers, loaders, and other handlers must wear:

- Coveralls over long-sleeved shirt and long pants
- Shoes plus socks
- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber
- Dust/Mist-filtering respirator or a NIOSH-approved respirator with any N, R, P, or HE filter

#### Applicators (Enclosed Cockpit)

##### While inside the cockpit must wear:

- Long-sleeved shirt and long pants
- Shoes plus socks

##### When entering or leaving the cockpit must also wear:

- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber.

**NOTE:** Once inside the cockpit, applicator must remove gloves and store them in a chemical-resistant container such as a plastic bag.

##### Flaggers must wear:

- Long-sleeved shirt and long pants
- Shoes plus socks
- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

### Engineering Controls

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170-240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

### User Safety Recommendations

#### Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothes immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

### Environmental Hazards

~~This pesticide is toxic to fish, birds, mammals, and aquatic invertebrates. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash water or rinsate.~~

~~This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow drift to blooming crops or weeds if bees are visiting the treatment area.~~

### Physical or Chemical Hazards

Do not use or store near heat or open flame.

REPLACE with:

Author: tham02 Subject: Inserted Text Date: 4/23/2013 3:47:20 PM

"This pesticide is toxic to fish, birds, mammals, and aquatic invertebrates. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash water or rinsate.

This product is highly toxic to bees if exposed to direct treatment or residues on blooming crops or other plants, for up to 24 hours after application. To reduce potential exposure to pollinators that may be visiting the treatment area, do not apply this product or allow drift to blooming, pollen-shedding, or nectar producing parts of plants during this time period."

This page contains no comments

#### **CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY**

**NOTICE:** Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, LLC or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions, or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and (2) Buyer and User assume the risk of any such use. TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.



This page contains no comments

#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Enfold must be used only in accordance with directions on this label or in separately published Syngenta supplemental labeling for this product.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

#### **AGRICULTURAL USE REQUIREMENTS**

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber, or butyl rubber
- Shoes plus socks
- Protective eyewear

This page contains no comments

**FAILURE TO FOLLOW DIRECTIONS AND PRECAUTIONS ON THIS LABEL MAY  
RESULT IN POOR INSECT CONTROL.**

---

**GENERAL INFORMATION**

---

Enfold is a selective insecticide for use on herbaceous and woody ornamental plants grown outdoors (in containers or in the ground) in commercial nursery production. Woody ornamentals include (but are not limited to) shrubs, non-bearing fruit and nut trees, Christmas trees, forest seedlings, and shade trees.

Enfold controls the larval stages (worms/caterpillars) of listed lepidopteran species and suppresses Liriomyza leafminer, Tetranychid mites and pear psylla. Enfold has contact activity, but is most efficacious when ingested by the pest. Shortly after exposure to Enfold, affected larvae are paralyzed, stop feeding, and subsequently die after 2-4 days.

- Apply Enfold to plant foliage when larvae first appear (immediately after egg hatch), but before populations reach damaging levels. Target Enfold applications at small (1/4 inch in length) larvae.
- Treatments must be made before larvae penetrate plant parts or before larvae begin webbing and sheltering.
- Thorough spray coverage is essential for optimum performance. Apply Enfold in sufficient water to ensure good coverage of all plant surfaces. The use of greater water volumes will generally result in better coverage, especially under adverse conditions (e.g., hot, dry) or when the plant canopy is dense.

**Resistance Management**

Enfold is a Group 6 insecticide (contains the active ingredient emamectin benzoate).

Because of the inherent risks of resistance development to any product, it is strongly advised that Enfold be used in a sound resistance management program. Treatment may not be effective against labeled pests if tolerant strains of insects or mites develop. When applying Enfold to plants that are hosts of labeled pests and these labeled pests have multiple generations per crop per year, use resistance management practices.

**Resistance management practices** may include, but are not limited to:

- Rotating Enfold with other products with different modes of action
- Avoiding treatment of successive pest generations with Enfold
- Using labeled rates at the specified spray intervals
- Using non-chemical alternatives such as beneficial arthropods
- Rotating susceptible to non-susceptible plants
- Using various cultural practices

This page contains no comments

For additional information regarding the implementation of these or other resistance management practices, consult your local agricultural advisor or company representative.

---

## APPLICATION PROCEDURES

---

### Application Prohibitions:

- **Chemigation:** Do not apply this product through any type of irrigation system.
- **State Restriction:** Do not apply Enfold with aircraft in New York State.

### Spray Equipment

Apply by ground, airblast sprayer or aircraft. Spray equipment configuration should be arranged to provide accurate, uniform, and thorough coverage of the target crop and minimize potential for spray drift. Use spray nozzles that provide medium to fine-sized droplets. To ensure accuracy, calibrate sprayer before each use. For spray equipment and calibration information, consult sprayer manufacturers and/or state recommendations. All ground and aerial application equipment must be properly maintained and calibrated using appropriate carriers.

### Spray Volume

- Applications using sufficient water volume for thorough and uniform coverage of the target crop provide the most effective pest control.
- Avoid application when uniform coverage is not possible or if excessive spray drift or inversion is possible.

---

## SPRAY DRIFT

---

**NOTE:** When states have more stringent regulations, they must be observed.

### Spray Drift Precautions – Aircraft and Ground Application Equipment

Apply Enfold only when wind velocity favors on-target product deposition (approximately 3 to 10 mph).

- **Do not** apply with ground application equipment within 25 ft. of or with aircraft within 150 ft. of lakes, reservoirs, rivers, permanent streams, marshes, pot holes, natural ponds, estuaries, or commercial fish farm ponds.
- **Do not** cultivate within 25 ft. of the aquatic area to allow growth of a vegetative filter strip.



This page contains no comments

- Do not allow this product to drift onto non-target areas. Drift may result in illegal residues or injury to non-target species. Risk of exposure to sensitive areas can be reduced by applying this product when the wind direction is away from the sensitive area.
- Do not apply when the weather conditions may cause drift:
  - Avoid application when the temperature is high and/or the humidity is low. These conditions increase the evaporation of spray droplets and the likelihood of drift to aquatic areas.
  - Do not apply when wind speed or wind gusts are greater than 10 mph.
  - Do not apply when wind speed is below 2 mph because wind direction will vary and there is a high potential for inversion.

#### **Spray Drift Precautions (Aerial Application)**

##### **Responsibility**

Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment- and weather-related factors determines the potential for spray drift. The applicator is responsible for considering all of these factors when making application decisions.

##### **Drift Management Requirements**

The following drift management requirements must be followed to avoid off-target movement from aerial applications to non-target plants.

- **Outermost Nozzle Distance**  
The distance of the outermost nozzles on the boom must not exceed  $\frac{3}{4}$  the length of the wingspan or rotor.
- **Nozzle Direction**  
Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees.
- **Maximum Wind Speed**  
Do not apply when wind speed is greater than 10 mph.
- **Droplet Size**  
The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential but will not prevent drift if applications are made improperly, or under unfavorable

This page contains no comments

environmental conditions. (See **Wind, Temperature and Humidity**, and **Temperature Inversions** sections.)

- **Controlling Droplet Size**

- Volume**

- Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets.

- Pressure**

- Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types, lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure.

- Number of Nozzles**

- Use the minimum number of nozzles that provide uniform coverage.

- Nozzle Orientation**

- Orienting nozzles so that the spray is released parallel to the air stream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential.

- Nozzle Type**

- Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid-stream nozzles oriented straight back produce the largest droplets and the lowest drift.

- **Boom Length**

- For some use patterns, reducing the effective boom length to less than  $\frac{1}{4}$  of the wingspan or rotor length may further reduce drift without reducing swath width.

- **Application Height**

- Applications should not be made at a height greater than 10 ft. above the top of the target plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind.

- **Swath Adjustment**

- When applications are made with a cross wind, the swath will be displaced downwind. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind.

- **Wind**

- Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application must be avoided below 2 mph due to variable wind

This page contains no comments

direction and high inversion potential. **NOTE:** Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift.

- **Temperature and Humidity**

To compensate for evaporation when applying Enfold in low relative humidity, set up equipment to produce larger droplets. Evaporation of droplets is most severe when conditions are both hot and dry.

- **Temperature Inversions**

Enfold must not be applied during a temperature inversion because the potential for drift is high. Temperature inversions restrict vertical air mixing, and this causes small, suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds that are common during inversions. Temperature inversions are characterized by temperatures that increase with altitude and are common on nights with limited cloud cover and light to no wind. Inversions begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, the movement of smoke from a ground source or an aircraft smoke generator can also identify inversions. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates, indicates good vertical air mixing.

---

#### **MIXING PROCEDURES**

---

1. Thoroughly clean spray equipment before using this product.
2. Prepare no more spray mixture than is needed for the immediate application.
3. Keep product container tightly closed when not in use.
4. Agitate the spray solution before and during application.
5. Do not let the spray mixture stand overnight in the spray tank.
6. Flush the spray equipment thoroughly following each use and apply rinsate to a previously treated area.

#### **Mixing Instructions: Enfold Alone**

1. Add 1/3 of the required amount of water to the spray or mixing tank.
2. With the agitator running, add Enfold into the spray tank.
3. Continue agitation while adding the remainder of the water.
4. Begin application of the solution after Enfold has completely dispersed into the mix water.
5. Maintain agitation until all of the mixture has been applied.

**Note:** Do not use liquid fertilizer as a carrier for Enfold.



This page contains no comments

## Enfold - Tank Mixtures

### Compatibility

Enfold is compatible with most insecticide, fungicide, and foliar nutrient products. However, before tank mixing Enfold use a jar test, as described below, to test the physical compatibility of Enfold with tank mix partners.

1. Using a quart jar, add the proportionate amounts of the products to 1 qt. of water. Add wettable powders and water-dispersible granular products first, then liquid flowables, and emulsifiable concentrates last.
2. After thoroughly mixing, let the mixture stand for at least 5 minutes. If the combination remains mixed or can be remixed readily, it is physically compatible.
3. If compatibility is acceptable, follow the instructions in **Mixing Instructions: Enfold Tank Mixtures**.

### NOTE:

- If using Enfold in a tank mixture:
  - Do not mix with any product that prohibits such mixing.
  - Observe all directions for use, crop/sites, use rates, dilution rates, precautions, and limitations that appear on the tank mix product label.
  - Do not exceed any labeled use rate.
  - Follow the most restrictive label precautions and limitations.
- Tank mixtures or other applications of products referenced on this label are permitted only in those states in which the referenced products are labeled.

### Mixing Instructions: Enfold Tank Mixtures

1. Add 1/3 of the required amount of water to the mix tank.
2. Start the agitator running before adding any tank-mix partners.
3. When using Enfold in tank mixtures:
  - a. All products in water-soluble packaging should be added to the tank before any other tank-mix partner, including Enfold.
  - b. Allow the water-soluble packaging to completely dissolve and the product(s) to completely disperse before adding any other tank-mix partner to the tank.
  - c. Then add other tank-mix partners in this order: wettable powders, wettable granules (dry flowables), liquid flowables, liquids and emulsifiable concentrates. Always allow each tank mix partner to become fully dispersed before adding the next product.
4. Provide sufficient agitation while adding the remainder of the water.
5. Maintain agitation until all the mixture has been applied.

This page contains no comments

---

#### USE DIRECTIONS

---

- **Location Prohibition:** Do not use Enfold in greenhouses.
- **Number of Applications:** Do not apply more than 3 sequential applications of Enfold. Rotate to another insect control product with a different mode of action for at least two applications.
- **Adjuvant Recommendation:** Thorough spray coverage of plant foliage is essential for optimum control. To provide optimum coverage and insect control, the use of a penetrating type spray adjuvant such as horticultural spray oil (not a dormant oil) or a nonionic surfactant at the manufacturer's suggested rate is recommended. Do not use a sticker/binder type adjuvant or tank mix with products that contain a sticker/binder component in the formulation because this may reduce Enfold insect control.
- **Application following failure of another insecticide:** Do not apply Enfold following the failure of another product if the larvae are large ( $>1/4$  inch long).

#### Plant Safety

**NOTICE TO USER:** Plant tolerance to Enfold has been found to be acceptable for many genera and species. Due to the large number of species and varieties of ornamentals and nursery plants, it is impossible to test every one for tolerance to Enfold. The professional user should determine if Enfold can be used safely prior to commercial use. In a small area, test the recommended rates on a small number of plants for phytotoxicity prior to widespread use.

**Tank Mixture:** The safety of all potential tank mixes on all plants may not have been tested. Before applying any tank mixture not specifically recommended on this label, the safety to the target plants should be confirmed.

This page contains no comments

| Pest                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | oz. Product/A per Application | Instructions                                                                                                                                                                                                    |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Beet armyworm<br>Cabbage looper<br>Cabbage webworm<br>Corn earworm<br>Cross-striped cabbageworm<br>Diamondback moth<br>Fall armyworm<br>Imported cabbageworm<br>Southern armyworm<br>Tobacco budworm<br>Tobacco hornworm<br>Tomato hornworm<br>Tomato fruitworm<br>Tomato pinworm<br>Yellowstriped armyworm                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 2.4-4.8 oz./A                 | Apply when larvae are first observed.<br>Application may be repeated at a 7- to 14-day interval to maintain control.<br><br>Use 2.4 oz./A for low to moderate infestations and 4.8 oz./A for high infestations. |
| Alfalfa looper<br>Apple pandemis<br>Bagworm<br>Bud moths:<br>eyespotted<br>tufted apple<br>Cabbage looper<br>Cankerworm species<br>Codling moth<br>Common winter moth<br>European winter moth<br>Fall webworm<br>Filbertworm<br>Fruitworms:<br>cherry<br>green species<br>laconobia<br>Genista caterpillar<br>Gypsy moth<br>Hickory shuckworm<br>Leafminers:<br>blister moth species<br>tentiform species<br>Leafrollers:<br>filbert<br>fruitree<br>obliquebanded<br>omnivorous<br>redbanded<br>variegated<br>Lesser appleworm<br>Liriomyza leafminers <sup>1</sup><br>Mimosa webworm<br>Navel orangeworm<br>Peach twig borer<br>Omnivorous leaflier<br>Orange tortrix<br>Oriental fruit moth<br>Pear psylla <sup>2</sup><br>Pecan bud moth<br>Pecan casebearer species | 3.2-4.8 oz./A                 | Apply when larvae are first observed.<br>Application may be repeated at a 7- to 14-day interval to maintain control.<br><br>Use 3.2 oz./A for low to moderate infestations and 4.8 oz./A for high infestations. |



This page contains no comments

|                             |  |  |
|-----------------------------|--|--|
| Pecan serpentine leafminer  |  |  |
| Redhumped caterpillar       |  |  |
| Soybean looper              |  |  |
| Spider mites <sup>2,3</sup> |  |  |
| Spruce budworm              |  |  |
| Tent Caterpillars:          |  |  |
| Eastern                     |  |  |
| Forest                      |  |  |
| Walnut caterpillar          |  |  |

<sup>1</sup> Enfold provides suppression of *Liriomyza trifolii*, *Liriomyza sativae*, and *Liriomyza hudsonensis* populations. Suppression means either erratic control ranging from good to poor or consistent control at a level below that which is generally considered acceptable for commercial control.

<sup>2</sup> Enfold provides suppression. Suppression means either erratic control ranging from good to poor or consistent control at a level below that which is generally considered acceptable for commercial control.

<sup>3</sup> Refers to phytophagous mites in the Acari subfamily Tetranychinae.

#### Enfold Mixing Aid and Spray Volume Dilution Chart

Ounces of Enfold Added to Specified Spray Solution Mix Volumes Based on Listed Product Application Rate and Application Volume

| Application Volume<br>(Gallons Per Acre) | Application Rate<br>(Ounces of Product<br>Per Acre) | 25 Gallons of<br>Finished Spray | 50 Gallons of<br>Finished<br>Spray | 100 Gallons of<br>Finished<br>Spray |
|------------------------------------------|-----------------------------------------------------|---------------------------------|------------------------------------|-------------------------------------|
| 50                                       | 2.4                                                 | 1.2                             | 2.4                                | 4.8                                 |
| 50                                       | 3.2                                                 | 1.6                             | 3.2                                | 6.4                                 |
| 50                                       | 4.8                                                 | 2.4                             | 4.8                                | 9.6                                 |
| 100                                      | 2.4                                                 | 0.6                             | 1.2                                | 2.4                                 |
| 100                                      | 3.2                                                 | 0.8                             | 1.6                                | 3.2                                 |
| 100                                      | 4.8                                                 | 1.2                             | 2.4                                | 4.8                                 |
| 150                                      | 2.4                                                 | 0.4                             | 0.6                                | 1.6                                 |
| 150                                      | 3.2                                                 | 0.53                            | 1.06                               | 2.1                                 |
| 150                                      | 4.8                                                 | 0.8                             | 1.6                                | 3.2                                 |
| 200                                      | 2.4                                                 | 0.3                             | 0.6                                | 1.2                                 |
| 200                                      | 3.2                                                 | 0.4                             | 0.8                                | 1.6                                 |
| 200                                      | 4.8                                                 | 0.6                             | 1.2                                | 2.4                                 |
| 250                                      | 2.4                                                 | 0.24                            | 0.48                               | 0.96                                |
| 250                                      | 3.2                                                 | 0.32                            | 0.64                               | 1.26                                |
| 250                                      | 4.8                                                 | 0.48                            | 0.96                               | 1.92                                |
| 300                                      | 2.4                                                 | 0.2                             | 0.4                                | 0.8                                 |
| 300                                      | 3.2                                                 | 0.28                            | 0.53                               | 1.06                                |
| 300                                      | 4.8                                                 | 0.4                             | 0.8                                | 1.6                                 |

This page contains no comments

1 ounce of Enfold = 9.5 teaspoons

Do not use household measuring utensils to measure Enfold.

#### Use Restrictions

- Allow a minimum of 7 days between applications.
- Do not apply more than 28.8 oz./A per year.

---

#### STORAGE AND DISPOSAL

---

Do not contaminate water, food, or feed by storage and disposal.

##### Pesticide Storage

Store in a cool, dry area under lock and key. Post as a pesticide storage area. Always store pesticides in the original container. Store away from food, pet food, feed, seed, fertilizers, and veterinary supplies. Place liquid formulations on lower shelves and dry formulations above.

##### Pesticide Disposal

Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

##### Container Handling

~~Non-refillable container:~~ Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration.

---

Enfold™, the ALLIANCE FRAME, the SYNGENTA Logo and the PURPOSE ICON are Trademarks of a Syngenta Group Company

©2012 Syngenta

This page contains no comments

For non-emergency (e.g., current product information) call  
Syngenta Crop Protection at 1-800-334-9481.

Manufactured for:  
Syngenta Crop Protection, LLC  
P.O. Box 18300  
Greensboro, North Carolina 27419-8300  
SCP



This page contains no comments

(Non-detachable Container Label)

**RESTRICTED USE PESTICIDE**  
**TOXIC TO FISH, MAMMALS, AND AQUATIC ORGANISMS**  
FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR  
DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S  
CERTIFICATION.

**Enfold™**

Insecticide

**GROUP 6 INSECTICIDE**

For control of listed lepidopterous larvae (worms/caterpillars) and suppression of  
leafminers and spider mites on outdoor-grown plants in commercial nursery production

|                                          |        |
|------------------------------------------|--------|
| Active Ingredient:                       |        |
| Emamectin benzoate (CAS No. 155569-91-8) | 5.0%   |
| Other Ingredients:                       | 95.0%  |
| Total:                                   | 100.0% |

Enfold Insecticide is a soluble granule containing 5% emamectin benzoate.

**KEEP OUT OF REACH OF CHILDREN.**

**CAUTION**

See additional precautionary statements and directions for use in booklet.

**AGRICULTURAL USE REQUIREMENTS**

Use this product only in accordance with its labeling and with the Worker Protection  
Standard, 40 CFR part 170. Refer to supplemental labeling under "Agricultural Use  
Requirements" in the Directions for Use section for information about this standard.

EPA Reg. No. 100-XXXX

EPA Est. XXXXX

Product of XXXXX  
Formulated in XXXXX

SCP

Net Weight

Refer to **FIRST AID** section in attached booklet for additional precautionary statements.

## PRECAUTIONARY STATEMENTS

### Hazards to Humans and Domestic Animals

#### CAUTION

Harmful if swallowed, inhaled, or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Avoid breathing dust or spray mist. Prolonged or frequently repeated exposure may cause allergic skin reactions in some individuals.

~~This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow drift to blooming crops or weeds if bees are visiting the treatment area.~~

#### Physical or Chemical Hazards

Do not use or store near heat or open flame.

## STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

### Pesticide Storage

Store in a cool, dry area under lock and key. Post as a pesticide storage area. Always store pesticides in the original container. Store away from food, pet food, feed, seed, fertilizers, and veterinary supplies. Place liquid formulations on lower shelves and dry formulations above.

### Pesticide Disposal

Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

### Container Handling

Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: empty the remaining

#### Environmental Hazards

This pesticide is toxic to fish, birds, mammals, and aquatic invertebrates. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash water or rinsate.

This product is highly toxic to bees if exposed to direct treatment or residues on blooming crops or other plants, for up to 24 hours after application. To reduce potential exposure to pollinators that may be visiting the treatment area, do not apply this product or allow drift to blooming, pollen-shedding, or nectar producing parts of plants during this time period."

This page contains no comments

contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration.

**Chemigation: Do not apply this product through any type of irrigation system.**

Enfold™ and the SYNGENTA Logo are Trademarks of a Syngenta Group Company.

©2012 Syngenta

Manufactured for:  
Syngenta Crop Protection, LLC  
P.O. Box 18300  
Greensboro, North Carolina 27419-8300

SCP

Enfold (draft new product) – pl – 5/13/11  
000100-XXXXX.20110518.ENFOLD\_NEW-PRODUCT\_MAY2011.pdf

Enfold (draft new product-version b) CLEAN – pl – 9/21/11  
000100-XXXXX.20110921.ENFOLD\_NEW-PRODUCT-B\_SEP2011.pdf

Enfold (draft new product-c) CLEAN – pl – 3/22/12  
000100-XXXXX.20120322.ENFOLD\_NEW\_C\_MAR2012.pdf

Enfold (draft new product-d) CLEAN – pl – 3/27/12  
000100-XXXXX.20120327.ENFOLD\_NEW\_D\_MAR2012.pdf





**Re: emamectin - drinking water driver** 

**Rosanna Louie-Juzwiak** to: Thomas Harris

10/16/2012 03:05 PM

Cc: Andrew Ertman, Barbara Madden, Dana Spatz, James Hetrick

From: Rosanna Louie-Juzwiak/DC/USEPA/US  
To: Thomas Harris/DC/USEPA/US@EPA  
Cc: Andrew Ertman/DC/USEPA/US@EPA, Barbara Madden/DC/USEPA/US@EPA, Dana Spatz/DC/USEPA/US@EPA, James Hetrick/DC/USEPA/US@EPA

Tom,

To confirm, the (outdoor) ornamentals use is still the driver exposure scenario, relative to the other uses. Although the rates are the same across several crops/uses, the exposure scenario modeled can impact the resulting EDWCs (refer to Table A1 in Appendix 1 of the drinking water assessment).

Please let me know if you have any other questions. Thanks,  
Rosanna

Rosanna Louie-Juzwiak      Tom, The driver for DW is determined bas...

10/15/2012 12:44:52 PM

From: Rosanna Louie-Juzwiak/DC/USEPA/US  
To: Thomas Harris/DC/USEPA/US@EPA  
Cc: Andrew Ertman/DC/USEPA/US@EPA, Barbara Madden/DC/USEPA/US@EPA, Thomas Harris/DC/USEPA/US@EPA, Dana Spatz/DC/USEPA/US@EPA  
Date: 10/15/2012 12:44 PM  
Subject: Re: emamectin - drinking water driver

---

Tom,

The driver for DW is determined based on the use that would result in the highest concentration that could occur in drinking water.

I would need to look back at previously assessed uses, as there was an issue (subsequently reconciled) concerning the application rates for some of the previously assessed crops that were identified as the driver, relative to the last drinking water assessment that were in the files. Given that ornamentals are comparable to other rates, I'd like to confirm the other EDWCs, so I'll get back to you this week.

Finally, your question concerning the math pertains to a rounding issue. So, the seasonal value is actually correct, and each application rate only goes out to three decimal places.

Let me know if you have any other questions,  
Rosanna

Thomas Harris      Rosanna, I was looking through the emamectin...

10/11/2012 04:19:12 PM

From: Thomas Harris/DC/USEPA/US  
To: Rosanna Louie-Juzwiak/DC/USEPA/US@EPA  
Cc: Andrew Ertman/DC/USEPA/US@EPA, Barbara Madden/DC/USEPA/US@EPA, John Hebert/DC/USEPA/US@EPA  
Date: 10/11/2012 04:19 PM  
Subject: emamectin - drinking water driver

---

Rosanna,

I was looking through the emamectin cucurbit/ornamental reviews and I have a question about the

drinking water memo (5/30/12 seems to be the latest version).

The memo states that the ornamentals are the drinking water driver. Why? The ornamental rate is 4.8 oz product/A/application with a max of 28.8 oz prod/A/year. This is the same as the currently registered Brassica vegetables (head/stem & leafy subgroups), fruiting vegetables, and leafy vegetables (ex. Brassica).

Then again, does it really matter that you've tagged ornamentals as the driver? The net a.i. rates you've used are 0.015 lb ai/A/application with a max of 0.094 lb a.i./A/year. Actually, I think that's a math error since I calculate the vegetables out to a max of 0.090 lb a.i./A/year. But is that tiny 0.004 difference resulting in worse DW numbers than the previously approved veggies? Note: The tree nuts has same individual rate (4.8 oz prod) but half the seasonal max (14.4 oz prod).

There's probably more to this than just the rates. Please let me know how the DW driver is determined.

Tom Harris  
EPA/OPPTS/OPP/RD/IRB  
voice: (703) 308-9423  
fax: (703) 308-0029  
harris.thomas@epa.gov  
visit <http://www.epa.gov/pesticides>

Donald Sipe, PretiFlaherty (on behalf of American Forest and Paper Association)  
Richard Smead, Director, Navigant Consulting, Inc. (on behalf of America's Natural Gas Alliance)  
Andrew Soto, Senior Managing Counsel, American Gas Association

[FR Doc. 2012-20596 Filed 8-21-12; 8:45 am]

BILLING CODE 6717-01-P

## ENVIRONMENTAL PROTECTION AGENCY

[FRL-9717-6]

### Notice of Approval of Title V Operating Permit for Peabody Western Coal Company (Navajo Nation EPA No. NN-OP 08-010)

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of final action.

**SUMMARY:** This notice announces that the Navajo Nation Environmental Protection Agency ("NNEPA"), acting with authority from the United States Environmental Protection Agency ("EPA") delegated pursuant to 40 C.F.R. Part 71, has issued a federal Clean Air Act Title V operating permit to Peabody Western Coal Company ("Peabody") governing air emissions from Peabody's mining operation at the Kayenta Mine, Black Mesa Complex in Arizona on the reservation of the Navajo Nation.

**DATES:** NNEPA, acting as EPA's delegate, issued notice of a final permit decision on May 21, 2012. Certain portions of the permit became effective on April 14, 2011. All other provisions of the permit became effective on March 13, 2012 after the Environmental Appeals Board denied Peabody's petition for review. Pursuant to section 307(b)(1) of the Clean Air Act, 42 U.S.C. 7607(b)(1), judicial review of this permit decision, to the extent it is available, may be sought by filing a petition for review in the United States Court of Appeals for the Ninth Circuit by October 22, 2012.

**ADDRESSES:** The documents relevant to the above-referenced permits are available for public inspection during normal business hours at the following address: U.S. Environmental Protection Agency, Region 9, 75 Hawthorne Street, San Francisco, CA 94105. To arrange for viewing of these documents call Roger Kohn at (415) 972-3973.

**FOR FURTHER INFORMATION CONTACT:** Roger Kohn, Air Division Permits Office, U.S. Environmental Protection Agency, Region 9, 75 Hawthorne Street, San Francisco, CA 94105.

Charlene Nelson, Navajo Nation Air Quality Control Program, Operating Permits Section, P.O. Box 529, Fort Defiance, AZ 86504.

Anyone who wishes to review the EPA Environmental Appeals Board decision described below can obtain it at <http://www.epa.gov/eab/>.

**Notice of Final Action and Supplementary Information:** NNEPA issued notice of a final revised permit decision to Peabody for its surface coal mining operations on the Navajo reservation, Title V Operating Permit No. NN-OP 08-010 ("Peabody permit"), on May 21, 2012. The Peabody revised permit was initially issued by NNEPA on April 14, 2011. EPA's Environmental Appeals Board ("EAB") received a petition for review by Peabody of this revised permit on May 16, 2011. On March 13, 2012, the EAB issued an order denying review of the petition. *See In re Peabody Western Coal Company, CAA Appeal No. 11-01 (EAB March 13, 2012) (Order Denying Petition for Review).* The petition challenged, among other things, NNEPA's use of tribal law in issuing the permit and inclusion in the permit for conditions III(B), IV(C), IV(D), IV(E), IV(G), IV(H), IV(I), IV(K), IV(L), and IV(Q) tribal law citations in parallel with the federally enforceable 40 C.F.R. Part 71 requirements. After the EAB's denial of review, Peabody filed a motion with the EAB for reconsideration, which was denied on April 17, 2012. Pursuant to 40 C.F.R. 71.11(l)(5) and 124.19(f)(1), final agency action by EPA has occurred because agency review procedures before the EAB have been exhausted and NNEPA has issued a final permit decision.

Dated: August 8, 2012.

**Deborah Jordan,**

*Director, Air Division, Region IX.*

[FR Doc. 2012-20654 Filed 8-21-12; 8:45 am]

BILLING CODE 8560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2012-0390; FRL-9358-2]

### Pesticide Products; Receipt of Applications To Register New Uses

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice announces receipt of applications to register new uses for pesticide products containing currently registered active ingredients, pursuant to the provisions of section 3(c) of the Federal Insecticide, Fungicide, and

Rodenticide Act (FIFRA), as amended. EPA is publishing this Notice of such applications, pursuant to section 3(c)(4) of FIFRA.

**DATES:** Comments must be received on or before September 21, 2012.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2012-0390 by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- **Mail:** OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001.

- **Hand Delivery:** To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** A contact person is listed at the end of each registration application summary and may be contacted by telephone or email. The mailing address for each contact person listed is Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001.

## SUPPLEMENTARY INFORMATION:

### I. General Information

#### A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American



Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. What should I consider as I prepare my comments for EPA?*

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number). If you are commenting on a docket that addresses multiple products, please indicate to which registration number(s) your comment applies. If you are commenting on a docket that addresses multiple products, please indicate to which registration number(s) your comment applies.

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

**II. Registration Applications for New Uses**

EPA received applications as follows to register pesticide products containing currently registered active ingredients pursuant to the provisions of section 3(c) of FIFRA, and is publishing this Notice of such applications pursuant to section 3(c)(4) of FIFRA. Notice of receipt of these applications does not imply a decision by the Agency on the applications.

1. *Registration File Symbol:* 100-RURR. *Docket Number:* EPA-HQ-OPP-2011-0665. *Applicant:* Syngenta Crop Protection, LLC., P.O. Box 18300, Greensboro, NC 27419-8300. *Active ingredient:* Emamectin benzoate. *Product Type:* Insecticide. *Proposed Uses:* Outdoor commercial ornamental nursery production. *Contact:* Thomas Harris, (703) 308-9423, email address: [harris.thomas@epa.gov](mailto:harris.thomas@epa.gov).

2. *Registration Numbers:* 100-526, 100-541, and 100-603. *Docket Number:* EPA-HQ-OPP-2012-0301. *Applicant:* Syngenta Crop Protection, LLC., P.O. Box 18300, Greensboro, NC 27419-8300. *Active ingredient:* Simazine. *Product Type:* Herbicide. *Proposed Uses:* Citrus fruits (crop group 10), pome fruits (crop group 11), stone fruits (crop group 6) and tree nuts (crop group 14, except almond hulls). *Contact:* Hope Johnson, (703) 305-5410, email address: [johnson.hope@epa.gov](mailto:johnson.hope@epa.gov).

3. *Registration Numbers:* 100-902 and 100-904. *Docket Number:* EPA-HQ-OPP-2011-0665. *Applicant:* Syngenta Crop Protection, LLC., P.O. Box 18300, Greensboro, NC 27419-8300. *Active ingredient:* Emamectin benzoate. *Product Type:* Insecticide. *Proposed Uses:* Vegetable, cucurbit, group 9. *Contact:* Thomas Harris, (703) 308-9423, email address: [harris.thomas@epa.gov](mailto:harris.thomas@epa.gov).

4. *Registration Numbers:* 264-748 and 264-752. *Docket Number:* EPA-HQ-OPP-2012-0427. *Applicant:* Bayer CropScience LP., P.O. Box 12014, 2 T. W. Alexander Drive, Research Triangle Park, NC 27709. *Active ingredient:* Tebuconazole. *Product Type:* Fungicide. *Proposed Use:* Fruiting vegetables (group 8-10). *Contact:* Heather Garvie, (703) 308-0034, email address: [garvie.heather@epa.gov](mailto:garvie.heather@epa.gov).

5. *Registration Numbers:* 352-594, 352-597, 352-638, and 352-640. *Docket Number:* EPA-HQ-OPP-2012-0420. *Applicant:* DuPont Crop Protection, Stine-Haskell Research Center, P.O. Box 30, Newark, NJ 07114-0030. *Active ingredient:* Indoxacarb. *Product Type:*

Insecticide. *Proposed Uses:* Dry bean, snap bean, small fruit vine climbing (subgroup 13-07F), low growing berry (subgroup 13-07H). *Contact:* Julie Chao, (703) 308-8735, email address: [chao.julie@epa.gov](mailto:chao.julie@epa.gov).

6. *Registration Numbers:* 400-461, 400-466, and 400-487. *Docket Number:* EPA-HQ-OPP-2012-0515. *Applicant:* Chemtura Corporation, 199 Benson Road, Middlebury, CT 06749. *Active ingredient:* Diflubenzuron. *Product Type:* Insecticide. *Proposed Use:* Citrus (crop group 10-09). *Contact:* Autumn Metzger, (703) 305-5314, email address: [metzger.autumn@epa.gov](mailto:metzger.autumn@epa.gov).

7. *Registration File Symbol:* 524-ANO. *Docket Number:* EPA-HQ-OPP-2012-0545. *Applicant:* Monsanto, 1300 I St., NW., Suite 450 East, Washington, DC 20005. *Active ingredient:* Dicamba. *Product Type:* Herbicide. *Proposed Use:* Dicamba-tolerant MON 87708 Soybeans. *Contact:* Michael Walsh, (703) 308-2972, email address: [walsh.michael@epa.gov](mailto:walsh.michael@epa.gov).

8. *Registration Numbers:* 5481-219 and 5481-430. *Docket Number:* EPA-HQ-OPP-2012-00203. *Applicant:* Amvac Chemical Company, 4695 MacArthur Court, Suite 1200, Newport Beach, CA 92660-1706. *Active ingredient:* 1-Naphthalenacetic Acid. *Product Type:* Fungicide. *Proposed Uses:* Avocado, mamey sapote, mango, rambutan; and pome fruit group 11-10. *Contact:* Rosemary Kearns, (703) 305-5611, email address: [kearns.rosemary@epa.gov](mailto:kearns.rosemary@epa.gov).

9. *Registration Numbers:* 5481-433 and 5481-533. *Docket Number:* EPA-HQ-OPP-2012-0203. *Applicant:* Amvac Chemical Company, 4695 MacArthur Court, Suite 1200, Newport Beach, CA 92660-1706. *Active ingredient:* 1-Naphthalenacetic Acid, Ethyl Ester. *Product Type:* Fungicide. *Proposed Uses:* Avocado, mamey sapote, mango, rambutan; and pome fruit group 11-10. *Contact:* Rosemary Kearns, (703) 305-5611, email address: [kearns.rosemary@epa.gov](mailto:kearns.rosemary@epa.gov).

10. *Registration Number:* 5481-541. *Docket Number:* EPA-HQ-OPP-2012-0203. *Applicant:* Amvac Chemical Company, 4695 MacArthur Court, Suite 1200, Newport Beach, CA 92660-1706. *Active ingredient:* 1-Naphthalenacetic Acid, Sodium Salt. *Product Type:* Fungicide. *Proposed Uses:* Avocado, mamey sapote, mango, rambutan; and pome fruit group 11-10. *Contact:* Rosemary Kearns, (703) 305-5611, email address: [kearns.rosemary@epa.gov](mailto:kearns.rosemary@epa.gov).

11. *Registration File Symbol:* 7969-GUL. *Docket Number:* EPA-HQ-OPP-2012-0492. *Applicant:* BASF Corporation, P.O. Box 13528, 26 Davis Drive, Research Triangle Park, NC

27709. *Active ingredient:* Dicamba. *Product Type:* Herbicide. *Proposed Uses:* Dicamba-tolerant MON 87708 Soybeans; and conventional crops, including asparagus, corn (field, seed, silage, and popcorn), cotton (conventional), grass grown for seed, proso millet, pasture hay, rangeland, farmstead (non-cropland), farmstead turf (non-cropland), Conservation Reserve Program, small grains (barley, oats, triticale, and wheat), sorghum, soybean (conventional), sugarcane, and sod farms. *Contact:* Michael Walsh, (703) 308-2972, email address: [walsh.michael@epa.gov](mailto:walsh.michael@epa.gov).

12. *Registration Numbers:* 7969-185, 7969-186, 7969-247, 7969-258, 7969-289, and 7969-291. *Docket Number:* EPA-HQ-OPP-2012-0549. *Applicant:* BASF Corporation, P.O. Box 13528, 26 Davis Drive, Research Triangle Park, NC 27709. *Active ingredient:* Pyraclostrobin. *Product Type:* Fungicide. *Proposed Use:* Sugarcane. *Contact:* Dominic Schuler, (703) 347-0260, email address: [schuler.dominic@epa.gov](mailto:schuler.dominic@epa.gov).

13. *Registration Numbers:* 59639-154 and 59639-166. *Docket Number:* EPA-HQ-OPP-2012-0419. *Applicant:* Valent U.S.A. Corporation, 1600 Riviera Ave., Suite 200, Walnut Creek, CA 94596. *Active ingredient:* Imazosulfuron. *Product Type:* Herbicide. *Proposed Uses:* Melons (cantaloupe, citron melon, muskmelon, watermelon); and vegetables, tuberous and corm (arracacha, arrowroot, Chinese artichoke, Jerusalem artichoke, edible Canna, bitter cassava, sweet cassava, chayote (root), chufa, dasheen, ginger, leren, potato, sweet potato, tanier, turmeric, yam bean, and true yam). *Contact:* Mindy Ondish, (703) 605-0723, email address: [ondish.mindy@epa.gov](mailto:ondish.mindy@epa.gov).

14. *Registration Number:* 62719-407. *Docket Number:* EPA-HQ-OPP-2012-0480. *Applicant:* Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268. *Active ingredient:* Myclobutanil. *Product Type:* Fungicide. *Proposed Use:* Formulation use into fungicide products. *Contact:* Marcel Howard, (703) 305-6784, email address: [howard.marcel@epa.gov](mailto:howard.marcel@epa.gov).

15. *Registration Number:* 62719-410. *Docket Number:* EPA-HQ-OPP-2012-0480. *Applicant:* Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268. *Active ingredient:* Myclobutanil. *Product Type:* Fungicide. *Proposed Use:* Grass grown for hay and forage. *Contact:* Marcel Howard, (703) 305-6784, email address: [howard.marcel@epa.gov](mailto:howard.marcel@epa.gov).

16. *Registration Numbers:* 63588-91, 63588-92, and 63588-93. *Docket*

*Number:* EPA-HQ-OPP-2012-0439. *Applicant:* K-I Chemical U.S.A., Inc., c/o Landis International, Inc., 3185 Madison Highway, P.O. Box 5126, Valdosta, GA 31603-5126. *Active ingredient:* Pyroxasulfone. *Product Type:* Herbicide. *Proposed Use:* Wheat. *Contact:* Michael Walsh, (703) 308-2972, email address: [walsh.michael@epa.gov](mailto:walsh.michael@epa.gov).

17. *Registration Numbers:* 63588-91, 63588-92, and 63588-93. *Docket Number:* EPA-HQ-OPP-2012-0514. *Applicant:* K-I Chemical U.S.A., Inc., c/o Landis International, Inc., 3185 Madison Highway, P.O. Box 5126, Valdosta, GA 31603-5126. *Active ingredient:* Pyroxasulfone. *Product Type:* Herbicide. *Proposed Use:* Cotton. *Contact:* Michael Walsh, (703) 308-2972, email address: [walsh.michael@epa.gov](mailto:walsh.michael@epa.gov).

18. *Registration Numbers:* 66330-64 and 66330-65. *Docket Number:* EPA-HQ-OPP-2012-0576. *Applicant:* Syngenta Crop Protection, LLC., P.O. Box 18300, Greensboro, NC 27419-8300. *Active ingredient:* Fluoxastrobin. *Product Type:* Fungicide. *Proposed Uses:* Melon, subgroup 9A; and sorghum. *Contact:* Heather Garvie, (703) 308-0034, email address: [garvie.heather@epa.gov](mailto:garvie.heather@epa.gov).

19. *Registration File Symbol:* 70506-EOA. *Docket Number:* EPA-HQ-OPP-2012-0431. *Applicant:* United Phosphorus, Inc., 630 Freedom Business Center, Suite 402, King of Prussia, PA 19406. *Active ingredient:* Endothall (dipotassium salt). *Product Type:* Herbicide. *Proposed Use:* Apples. *Contact:* Grant Rowland, (703) 347-0254, email address: [rowland.grant@epa.gov](mailto:rowland.grant@epa.gov).

#### List of Subjects

Environmental protection, Pesticides and pest.

Dated: August 14, 2012.

**Daniel J. Rosenblatt,**  
*Acting Director, Registration Division, Office of Pesticide Programs.*

[FR Doc. 2012-20666 Filed 8-21-12; 8:45 am]

**BILLING CODE 6560-50-P**

#### FEDERAL MARITIME COMMISSION

##### Notice of Agreement Filed

The Commission hereby gives notice of the filing of the following agreement under the Shipping Act of 1984. Interested parties may submit comments on the agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within ten days of the date this notice appears in the **Federal Register**. A copy of the

agreement is available through the Commission's Web site ([www.fmc.gov](http://www.fmc.gov)) or by contacting the Office of Agreements at (202) 523-5793 or [tradeanalysis@fmc.gov](mailto:tradeanalysis@fmc.gov).

*Agreement No.:* 012084-001.

*Title:* HLAG/Maersk Line Gulf-South America Slot Charter Agreement.

*Parties:* A.P. Moller-Maersk A/S and Hapag-Lloyd AG.

*Filing Party:* Wayne R. Rohde, Esq.; Cozen O'Connor; 1627 I Street NW., Suite 1100; Washington, DC 20006-4007.

*Synopsis:* The amendment would increase the amount of space to be chartered, provide for a new initial term of the agreement, and restates the agreement to correct a pagination error. The parties have requested expedited review.

By Order of the Federal Maritime Commission.

Dated: August 17, 2012.

**Karen V. Gregory,**  
*Secretary.*

[FR Doc. 2012-20652 Filed 8-21-12; 8:45 am]

**BILLING CODE 6730-01-P**

#### FEDERAL MARITIME COMMISSION

##### Ocean Transportation Intermediary License Applicants

The Commission gives notice that the following applicants have filed an application for an Ocean Transportation Intermediary (OTI) license as a Non-Vessel-Operating Common Carrier (NVO) and/or Ocean Freight Forwarder (OFF) pursuant to section 40901 of the Shipping Act of 1984 (46 U.S.C. 40101). Notice is also given of the filing of applications to amend an existing OTI license or the Qualifying Individual (QI) for a licensee.

Interested persons may contact the Office of Ocean Transportation Intermediaries, Federal Maritime Commission, Washington, DC 20573, by telephone at (202) 523-5843 or by email at [OTI@fmc.gov](mailto:OTI@fmc.gov).

Anselm K. Nwankwo dba Anze Global Logistics (NVO & OFF), 45 Harrison Street #A, Roslindale, MA 02131. Officer: Anselm K. Nwankwo, Sole Proprietor (Qualifying Individual), Application Type: New NVO & OFF License.

Armada AVS Corp (NVO), 709 E. Walnut Street Carson, CA 90746. Officers: Marina Agueeva, Secretary (Qualifying Individual), Vadim Kornilov, President. Application Type: New NVO License. Horizon Lines of Guam, LLC (NVO), 4064 Colony Road Suite 200,



FW: Revised Enfold labels- 100-RURR

tom.parshley

to:

Thomas Harris

03/28/2012 01:06 PM

Cc:

Data.Mgmt

Hide Details

From: <tom.parshley@syngenta.com>

To: Thomas Harris/DC/USEPA/US@EPA

Cc: <Data.Mgmt@syngenta.com>

## 2 Attachments



000100-XXXXXX.20120327.ENFOLD\_NEW\_D\_MAR2012-HI.pdf



000100-XXXXXX.20120327.ENFOLD\_NEW\_D\_MAR2012.pdf

Tom: as we discussed this morning, Syngenta noticed one other very minor change that needed to be made. Syngenta wishes the product's official name to be just Enfold. So we have deleted the word "Insecticide" from the product name throughout the label. "Insecticide" will still appear as a descriptor on the labeling front panel though. This label will supercede any previously submitted labeling. Thanks for your understanding.

Tom Parshley

---

**From:** Laird Patsy (ext) USGR

**Sent:** Tuesday, March 27, 2012 4:11 PM

**To:** Parshley Tom USGR

**Subject:** Revised Enfold labels

Tom,



I have removed "Insecticide" throughout the label. See if this works for you.

*Patsy*

---

*This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.*

(Booklet)

**RESTRICTED USE PESTICIDE**

**TOXIC TO FISH, MAMMALS, AND AQUATIC ORGANISMS**

FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION.

**Enfold™**

Insecticide

**GROUP 6 INSECTICIDE**

For control of listed lepidopterous larvae (worms/caterpillars) and suppression of leafminers and spider mites on outdoor-grown plants in commercial nursery production

Active Ingredient:

Emamectin benzoate (CAS No. 155569-91-8) .....5.0%

Other Ingredients: .....95.0%

Total: .....100.0%

Enfold is a soluble granule containing 5% emamectin benzoate.

**KEEP OUT OF REACH OF CHILDREN.**

**CAUTION**

See additional precautionary statements and directions for use in booklet.

EPA Reg. No. 100-XXXX

EPA Est. XXXXX

Product of XXXXX

Formulated in XXXXX

SCP

Net Weight



Enfold Insecticide - 100-RURR; revised draft labeling - OPP Decision  
Number D-449308

tom.parshley to: Thomas Harris  
Cc: steve.cosky, fred.pearson, Data.Mgmt

09/28/2011 10:04 AM

---

History: This message has been forwarded.

---

Tom: Attached are clean and highlighted label copy for the subject pending action that have been updated to add a dilution chart for the use directions. After filing the application, Syngenta realized that a dilution chart for users should have been included in the directions for use. The enclosed labeling reflects this revision. This chart does not change any of the rates for the uses on the labeling, rather it is meant to aid users. Please substitute the enclosed labeling for the labeling originally filed with the e-submission on May 17, 2011. This is a R230 PRIA action with a 15 month due date. Please let me know if there are any questions concerning this submission.

Best regards,

Tom

*This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.*



000100-XXXXX.20110921.ENFOLD\_NEW-PRODUCT-B\_SEP2011-HI.pdf



000100-XXXXX.20110921.ENFOLD\_NEW-PRODUCT-B\_SEP2011.pdf



(Booklet)

**RESTRICTED USE PESTICIDE**

**TOXIC TO FISH, MAMMALS, AND AQUATIC ORGANISMS**

FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION.

Enfold™  
Insecticide

**GROUP 6 INSECTICIDE**

For control of listed lepidopterous larvae (worms/caterpillars) and suppression of leafminers and spider mites on outdoor-grown plants in commercial nursery production

Active Ingredient:

Emamectin benzoate (CAS No. 155569-91-8) ..... 5.0%

Other Ingredients: ..... 95.0%

Total: ..... 100.0%

Enfold Insecticide is a soluble granule containing 5% emamectin benzoate.

**KEEP OUT OF REACH OF CHILDREN.**

**CAUTION**

See additional precautionary statements and directions for use in booklet.

EPA Reg. No. 100-XXXX

EPA Est. XXXXX

Product of XXXXX

Formulated in XXXXX

SCP

Net Weight

| <b>FIRST AID</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                            |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>If swallowed</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <ul style="list-style-type: none"> <li>• Call poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul> |
| <b>If in eyes</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>                                                    |
| <b>If on skin or clothing</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>                                                                                                                      |
| <b>If inhaled</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>                                                |
| <p align="center"><b>NOTE TO PHYSICIAN</b></p> <p>Early signs of intoxication include dilation of pupils, muscular incoordination, and muscular tremors. Vomiting within one-half hour of exposure can minimize toxicity following accidental ingestion of the product; rapidly after exposure (&lt; 15 minutes), administer repeatedly medical charcoal in a large quantity of water or ipecac.</p> <p>If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements.</p> <p>In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since emamectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic emamectin benzoate exposure.</p> |                                                                                                                                                                                                                                                                                                                                                            |
| <p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                            |



**HOT LINE NUMBER**

For 24-Hour Medical Emergency Assistance (Human or Animal)  
Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident)

Call

**1-800-888-8372**

---

**PRECAUTIONARY STATEMENTS**

---

**Hazards to Humans and Domestic Animals**

**CAUTION**

Harmful if swallowed, inhaled, or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Avoid breathing dust or spray mist. Prolonged or frequently repeated exposure may cause allergic skin reactions in some individuals.

**Personal Protective Equipment (PPE)**

- **Ground Application (except airblast sprayers):**

**Applicators, mixers, loaders, and other handlers must wear:**

- Long-sleeved shirt and long pants
- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber
- Shoes plus socks

- **Airblast Application:**

**Mixers, loaders, and other handlers must wear:**

- Long-sleeved shirt and long pants
- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber
- Shoes plus socks

**Applicators using OPEN CAB airblast sprayers must wear:**

- Coveralls over long-sleeved shirt and long pants
- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber
- Shoes plus socks



### **Applicators using ENCLOSED CAB airblast sprayers**

#### **While inside the cab must wear:**

- Long-sleeved shirt and long pants
- Shoes plus socks

#### **When entering or leaving the cab must also wear:**

- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber.

**NOTE:** Once inside the cab, applicator must remove gloves and store them in a chemical-resistant container such as a plastic bag.

- **Aerial application:**

#### **Mixers, loaders, and other handlers must wear:**

- Coveralls over long-sleeved shirt and long pants
- Shoes plus socks
- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber
- Dust/Mist-filtering respirator or a NIOSH-approved respirator with any N, R, P, or HE filter

### **Applicators (Enclosed Cockpit)**

#### **While inside the cockpit must wear:**

- Long-sleeved shirt and long pants
- Shoes plus socks

#### **When entering or leaving the cockpit must also wear:**

- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber.

**NOTE:** Once inside the cockpit, applicator must remove gloves and store them in a chemical-resistant container such as a plastic bag.

#### **Flaggers must wear:**

- Long-sleeved shirt and long pants
- Shoes plus socks
- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

## **Engineering Controls**

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170-240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

### **User Safety Recommendations**

#### **Users should:**

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothes immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

## **Environmental Hazards**

This pesticide is toxic to fish, birds, mammals, and aquatic invertebrates. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash water or rinsate.

This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow drift to blooming crops or weeds if bees are visiting the treatment area.

## **Physical or Chemical Hazards**

Do not use or store near heat or open flame.



---

## CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

---

**NOTICE:** Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, LLC or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions, or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and (2) Buyer and User assume the risk of any such use. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.**

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.



## **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Enfold Insecticide must be used only in accordance with directions on this label or in separately published Syngenta supplemental labeling for this product.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

### **AGRICULTURAL USE REQUIREMENTS**

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber, or butyl rubber
- Shoes plus socks
- Protective eyewear

**FAILURE TO FOLLOW DIRECTIONS AND PRECAUTIONS ON THIS LABEL MAY RESULT IN POOR INSECT CONTROL.**

---

**GENERAL INFORMATION**

---

Enfold Insecticide is a selective insecticide for use on herbaceous and woody ornamental plants grown outdoors (in containers or in the ground) in commercial nursery production. Woody ornamentals include (but are not limited to) shrubs, non-bearing fruit and nut trees, Christmas trees, forest seedlings, and shade trees.

Enfold Insecticide controls the larval stages (worms/caterpillars) of listed lepidopteran species and suppresses Liriomyza leafminer, Tetranychid mites and pear psylla. Enfold Insecticide has contact activity, but is most efficacious when ingested by the pest. Shortly after exposure to Enfold Insecticide, affected larvae are paralyzed, stop feeding, and subsequently die after 2-4 days.

- Apply Enfold Insecticide to plant foliage when larvae first appear (immediately after egg hatch), but before populations reach damaging levels. Target Enfold Insecticide applications at small (1/4 inch in length) larvae.
- Treatments must be made before larvae penetrate plant parts or before larvae begin webbing and sheltering.
- Thorough spray coverage is essential for optimum performance. Apply Enfold Insecticide in sufficient water to ensure good coverage of all plant surfaces. The use of greater water volumes will generally result in better coverage, especially under adverse conditions (e.g., hot, dry) or when the plant canopy is dense.

**Resistance Management**

Enfold Insecticide is a Group 6 insecticide (contains the active ingredient emamectin benzoate).

Because of the inherent risks of resistance development to any product, it is strongly advised that Enfold Insecticide be used in a sound resistance management program. Treatment may not be effective against labeled pests if tolerant strains of insects or mites develop. When applying Enfold Insecticide to plants that are hosts of labeled pests and these labeled pests have multiple generations per crop per year, use resistance management practices.

**Resistance management practices** may include, but are not limited to:

- Rotating Enfold Insecticide with other products with different modes of action
- Avoiding treatment of successive pest generations with Enfold Insecticide
- Using labeled rates at the specified spray intervals
- Using non-chemical alternatives such as beneficial arthropods
- Rotating susceptible to non-susceptible plants



- Using various cultural practices

For additional information regarding the implementation of these or other resistance management practices, consult your local agricultural advisor or company representative.

---

## APPLICATION PROCEDURES

---

### Application Prohibitions:

- **Chemigation:** Do not apply this product through any type of irrigation system.
- **State Restriction:** Do not apply Enfold Insecticide with aircraft in New York State.

### Spray Equipment

Apply by ground, airblast sprayer or aircraft. Spray equipment configuration should be arranged to provide accurate, uniform, and thorough coverage of the target crop and minimize potential for spray drift. Use spray nozzles that provide medium to fine-sized droplets. To ensure accuracy, calibrate sprayer before each use. For spray equipment and calibration information, consult sprayer manufacturers and/or state recommendations. All ground and aerial application equipment must be properly maintained and calibrated using appropriate carriers.

### Spray Volume

- Applications using sufficient water volume for thorough and uniform coverage of the target crop provide the most effective pest control.
- Avoid application when uniform coverage is not possible or if excessive spray drift or inversion is possible.

---

## SPRAY DRIFT

---

**NOTE:** When states have more stringent regulations, they must be observed.

### Spray Drift Precautions – Aircraft and Ground Application Equipment

Apply Enfold Insecticide only when wind velocity favors on-target product deposition (approximately 3 to 10 mph).

- **Do not** apply with ground application equipment within 25 ft. of or with aircraft within 150 ft. of lakes, reservoirs, rivers, permanent streams, marshes, pot holes, natural ponds, estuaries, or commercial fish farm ponds.



- **Do not** cultivate within 25 ft. of the aquatic area to allow growth of a vegetative filter strip.
- **Do not** allow this product to drift onto non-target areas. Drift may result in illegal residues or injury to non-target species. Risk of exposure to sensitive areas can be reduced by applying this product when the wind direction is away from the sensitive area.
- **Do not** apply when the weather conditions may cause drift:
  - Avoid application when the temperature is high and/or the humidity is low. These conditions increase the evaporation of spray droplets and the likelihood of drift to aquatic areas.
  - **Do not** apply when wind speed or wind gusts are greater than 10 mph.
  - **Do not** apply when wind speed is below 2 mph because wind direction will vary and there is a high potential for inversion.

### **Spray Drift Precautions (Aerial Application)**

#### **Responsibility**

Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment- and weather-related factors determines the potential for spray drift. The applicator is responsible for considering all of these factors when making application decisions.

#### **Drift Management Requirements**

The following drift management requirements must be followed to avoid off-target movement from aerial applications to non-target plants.

- **Outermost Nozzle Distance**  
The distance of the outermost nozzles on the boom must not exceed  $\frac{3}{4}$  the length of the wingspan or rotor.
- **Nozzle Direction**  
Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees.
- **Maximum Wind Speed**  
Do not apply when wind speed is greater than 10 mph.
- **Droplet Size**  
The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide

sufficient coverage and control. Applying larger droplets reduces drift potential but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions. (See **Wind, Temperature and Humidity**, and **Temperature Inversions** sections.)

- **Controlling Droplet Size**

- Volume**

- Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets.

- Pressure**

- Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types, lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure.

- Number of Nozzles**

- Use the minimum number of nozzles that provide uniform coverage.

- Nozzle Orientation**

- Orienting nozzles so that the spray is released parallel to the air stream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential.

- Nozzle Type**

- Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid-stream nozzles oriented straight back produce the largest droplets and the lowest drift.

- **Boom Length**

- For some use patterns, reducing the effective boom length to less than  $\frac{3}{4}$  of the wingspan or rotor length may further reduce drift without reducing swath width.

- **Application Height**

- Applications should not be made at a height greater than 10 ft. above the top of the target plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind.

- **Swath Adjustment**

- When applications are made with a cross wind, the swath will be displaced downwind. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind.



sufficient coverage and control. Applying larger droplets reduces drift potential but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions. (See **Wind, Temperature and Humidity**, and **Temperature Inversions** sections.)

- **Controlling Droplet Size**

- Volume**

- Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets.

- Pressure**

- Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types, lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure.

- Number of Nozzles**

- Use the minimum number of nozzles that provide uniform coverage.

- Nozzle Orientation**

- Orienting nozzles so that the spray is released parallel to the air stream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential.

- Nozzle Type**

- Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid-stream nozzles oriented straight back produce the largest droplets and the lowest drift.

- **Boom Length**

- For some use patterns, reducing the effective boom length to less than  $\frac{3}{4}$  of the wingspan or rotor length may further reduce drift without reducing swath width.

- **Application Height**

- Applications should not be made at a height greater than 10 ft. above the top of the target plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind.

- **Swath Adjustment**

- When applications are made with a cross wind, the swath will be displaced downwind. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind.



- **Wind**

Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application must be avoided below 2 mph due to variable wind direction and high inversion potential. **NOTE:** Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift.

- **Temperature and Humidity**

To compensate for evaporation when applying Enfold Insecticide in low relative humidity, set up equipment to produce larger droplets. Evaporation of droplets is most severe when conditions are both hot and dry.

- **Temperature Inversions**

Enfold Insecticide must not be applied during a temperature inversion because the potential for drift is high. Temperature inversions restrict vertical air mixing, and this causes small, suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds that are common during inversions. Temperature inversions are characterized by temperatures that increase with altitude and are common on nights with limited cloud cover and light to no wind. Inversions begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, the movement of smoke from a ground source or an aircraft smoke generator can also identify inversions. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates, indicates good vertical air mixing.

---

## **MIXING PROCEDURES**

---

1. Thoroughly clean spray equipment before using this product.
2. Prepare no more spray mixture than is needed for the immediate application.
3. Keep product container tightly closed when not in use.
4. Agitate the spray solution before and during application.
5. Do not let the spray mixture stand overnight in the spray tank.
6. Flush the spray equipment thoroughly following each use and apply rinsate to a previously treated area.

### **Mixing Instructions: Enfold Insecticide Alone**

1. Add 1/3 of the required amount of water to the spray or mixing tank.
2. With the agitator running, add Enfold Insecticide into the spray tank.
3. Continue agitation while adding the remainder of the water.



4. Begin application of the solution after Enfold Insecticide has completely dispersed into the mix water.
5. Maintain agitation until all of the mixture has been applied.

**Note:** Do not use liquid fertilizer as a carrier for Enfold Insecticide.

## **Enfold Insecticide - Tank Mixtures**

### **Compatibility**

Enfold Insecticide is compatible with most insecticide, fungicide, and foliar nutrient products. However, before tank mixing Enfold Insecticide use a jar test, as described below, to test the physical compatibility of Enfold Insecticide with tank mix partners.

1. Using a quart jar, add the proportionate amounts of the products to 1 qt. of water. Add wettable powders and water-dispersible granular products first, then liquid flowables, and emulsifiable concentrates last.
2. After thoroughly mixing, let the mixture stand for at least 5 minutes. If the combination remains mixed or can be remixed readily, it is physically compatible.
3. If compatibility is acceptable, follow the instructions in **Mixing Instructions: Enfold Insecticide Tank Mixtures**.

### **NOTE:**

- If using Enfold Insecticide in a tank mixture:
  - Do not mix with any product that prohibits such mixing.
  - Observe all directions for use, crop/sites, use rates, dilution ratios, precautions, and limitations that appear on the tank mix product label.
  - Do not exceed any labeled use rate.
  - Follow the most restrictive label precautions and limitations.
- Tank mixtures or other applications of products referenced on this label are permitted only in those states in which the referenced products are labeled.

### **Mixing Instructions: Enfold Insecticide Tank Mixtures**

1. Add 1/3 of the required amount of water to the mix tank.
2. Start the agitator running before adding any tank-mix partners.
3. When using Enfold Insecticide in tank mixtures:
  - a. All products in water-soluble packaging should be added to the tank before any other tank-mix partner, including Enfold Insecticide.
  - b. Allow the water-soluble packaging to completely dissolve and the product(s) to completely disperse before adding any other tank-mix partner to the tank.



- c. Then add other tank-mix partners in this order: wettable powders, wettable granules (dry flowables), liquid flowables, liquids and emulsifiable concentrates. Always allow each tank mix partner to become fully dispersed before adding the next product.
4. Provide sufficient agitation while adding the remainder of the water.
5. Maintain agitation until all the mixture has been applied.

---

## USE DIRECTIONS

---

- **Location Prohibition:** Do not use Enfold Insecticide in greenhouses.
- **Number of Applications:** Do not apply more than 3 sequential applications of Enfold Insecticide. Rotate to another insect control product with a different mode of action for at least two applications.
- **Adjuvant Recommendation:** Thorough spray coverage of plant foliage is essential for optimum control. To provide optimum coverage and insect control, the use of a penetrating type spray adjuvant such as horticultural spray oil (not a dormant oil) or a nonionic surfactant at the manufacturer's suggested rate is recommended. Do not use a sticker/binder type adjuvant or tank mix with products that contain a sticker/binder component in the formulation because this may reduce Enfold Insecticide insect control.
- **Application following failure of another insecticide:** Do not apply Enfold Insecticide following the failure of another product if the larvae are large (>1/4 inch long).

## Plant Safety

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>NOTICE TO USER:</b> Plant tolerance to Enfold Insecticide has been found to be acceptable for many genera and species. Due to the large number of species and varieties of ornamentals and nursery plants, it is impossible to test every one for tolerance to Enfold Insecticide. The professional user should determine if Enfold Insecticide can be used safely prior to commercial use. In a small area, test the recommended rates on a small number of plants for phytotoxicity prior to widespread use.</p> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

**Tank Mixture:** The safety of all potential tank mixes on all plants may not have been tested. Before applying any tank mixture not specifically recommended on this label, the safety to the target plants should be confirmed.



| Pest                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | oz. Product/A per Application | Instructions                                                                                                                                                                                                    |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Beet armyworm<br>Cabbage looper<br>Cabbage webworm<br>Corn earworm<br>Cross-striped cabbageworm<br>Diamondback moth<br>Fall armyworm<br>Imported cabbageworm<br>Southern armyworm<br>Tobacco budworm<br>Tobacco hornworm<br>Tomato hornworm<br>Tomato fruitworm<br>Tomato pinworm<br>Yellowstriped armyworm                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 2.4-4.8 oz./A                 | Apply when larvae are first observed.<br>Application may be repeated at a 7- to 14-day interval to maintain control.<br><br>Use 2.4 oz./A for low to moderate infestations and 4.8 oz./A for high infestations. |
| Alfalfa looper<br>Apple pandemis<br>Bagworm<br>Bud moths:<br>eyespotted<br>tufted apple<br>Cabbage looper<br>Cankerworm species<br>Codling moth<br>Common winter moth<br>European winter moth<br>Fall webworm<br>Filbertworm<br>Fruitworms:<br>cherry<br>green species<br>laconobia<br>Genista caterpillar<br>Gypsy moth<br>Hickory shuckworm<br>Leafminers:<br>blister moth species<br>tentiform species<br>Leafrollers:<br>filbert<br>fruittree<br>obliquebanded<br>omnivorous<br>redbanded<br>variegated<br>Lesser appleworm<br>Liriomyza leafminers <sup>1</sup><br>Mimosa webworm<br>Navel orangeworm<br>Peach twig borer<br>Omnivorous leaftier<br>Orange tortrix<br>Oriental fruit moth<br>Pear psylla <sup>2</sup><br>Pecan bud moth<br>Pecan casebearer species | 3.2-4.8 oz./A                 | Apply when larvae are first observed.<br>Application may be repeated at a 7- to 14-day interval to maintain control.<br><br>Use 3.2 oz./A for low to moderate infestations and 4.8 oz./A for high infestations. |

|                             |  |  |
|-----------------------------|--|--|
| Pecan serpentine leafminer  |  |  |
| Redhumped caterpillar       |  |  |
| Soybean looper              |  |  |
| Spider mites <sup>2,3</sup> |  |  |
| Spruce budworm              |  |  |
| Tent Caterpillars:          |  |  |
| Eastern                     |  |  |
| Forest                      |  |  |
| Walnut caterpillar          |  |  |

<sup>1</sup> Enfold Insecticide provides suppression of *Liriomyza trifolii*, *Liriomyza sativae*, and *Liriomyza hudriobrensis* populations. Suppression means either erratic control ranging from good to poor or consistent control at a level below that which is generally considered acceptable for commercial control.

<sup>2</sup> Enfold Insecticide provides suppression. Suppression means either erratic control ranging from good to poor or consistent control at a level below that which is generally considered acceptable for commercial control.

<sup>3</sup> Refers to phytophagous mites in the Acari subfamily Tetranychinae.

### Enfold Insecticide Mixing Aid and Spray Volume Dilution Chart

Ounces of Enfold Insecticide Added to Specified Spray Solution Mix Volumes Based on Listed Product Application Rate and Application Volume

| Application Volume<br>(Gallons Per Acre) | Application Rate<br>(Ounces of Product<br>Per Acre) | 25 Gallons of<br>Finished Spray | 50 Gallons of<br>Finished<br>Spray | 100 Gallons of<br>Finished<br>Spray |
|------------------------------------------|-----------------------------------------------------|---------------------------------|------------------------------------|-------------------------------------|
| 50                                       | 2.4                                                 | 1.2                             | 2.4                                | 4.8                                 |
| 50                                       | 3.2                                                 | 1.6                             | 3.2                                | 6.4                                 |
| 50                                       | 4.8                                                 | 2.4                             | 4.8                                | 9.6                                 |
| 100                                      | 2.4                                                 | 0.6                             | 1.2                                | 2.4                                 |
| 100                                      | 3.2                                                 | 0.8                             | 1.6                                | 3.2                                 |
| 100                                      | 4.8                                                 | 1.2                             | 2.4                                | 4.8                                 |
| 150                                      | 2.4                                                 | 0.4                             | 0.8                                | 1.6                                 |
| 150                                      | 3.2                                                 | 0.53                            | 1.06                               | 2.1                                 |
| 150                                      | 4.8                                                 | 0.8                             | 1.6                                | 3.2                                 |
| 200                                      | 2.4                                                 | 0.3                             | 0.6                                | 1.2                                 |
| 200                                      | 3.2                                                 | 0.4                             | 0.8                                | 1.6                                 |
| 200                                      | 4.8                                                 | 0.6                             | 1.2                                | 2.4                                 |
| 250                                      | 2.4                                                 | 0.24                            | 0.48                               | 0.96                                |
| 250                                      | 3.2                                                 | 0.32                            | 0.64                               | 1.28                                |
| 250                                      | 4.8                                                 | 0.48                            | 0.96                               | 1.92                                |
| 300                                      | 2.4                                                 | 0.2                             | 0.4                                | 0.8                                 |
| 300                                      | 3.2                                                 | 0.26                            | 0.53                               | 1.06                                |
| 300                                      | 4.8                                                 | 0.4                             | 0.8                                | 1.6                                 |



1 ounce of Enfold = 9.5 teaspoons

Do not use household measuring utensils to measure Enfold Insecticide.

### **Use Restrictions**

- Allow a minimum of 7 days between applications.
- Do not apply more than 28.8 oz./A per season.

---

## **STORAGE AND DISPOSAL**

---

Do not contaminate water, food, or feed by storage and disposal.

### **Pesticide Storage**

Store in a cool, dry area under lock and key. Post as a pesticide storage area. Always store pesticides in the original container. Store away from food, pet food, feed, seed, fertilizers, and veterinary supplies. Place liquid formulations on lower shelves and dry formulations above.

### **Pesticide Disposal**

Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

### **Container Handling**

Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container  $\frac{1}{4}$  full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration.

---

Enfold™, the ALLIANCE FRAME, the SYNGENTA Logo and the PURPOSE ICON are Trademarks of a Syngenta Group Company

©2011 Syngenta



For non-emergency (e.g., current product information) call  
Syngenta Crop Protection at 1-800-334-9481.

Manufactured for:  
Syngenta Crop Protection, LLC  
P.O. Box 18300  
Greensboro, North Carolina 27419-8300

SCP

(Non-detachable Container Label)

**RESTRICTED USE PESTICIDE**

**TOXIC TO FISH, MAMMALS, AND AQUATIC ORGANISMS**

FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION.

Enfold™  
Insecticide

**GROUP 6 INSECTICIDE**

For control of listed lepidopterous larvae (worms/caterpillars) and suppression of leafminers and spider mites on outdoor-grown plants in commercial nursery production

|                                                |        |
|------------------------------------------------|--------|
| Active Ingredient:                             |        |
| Emamectin benzoate (CAS No. 155569-91-8) ..... | 5.0%   |
| Other Ingredients:                             | 95.0%  |
| Total:                                         | 100.0% |

Enfold Insecticide is a soluble granule containing 5% emamectin benzoate.

**KEEP OUT OF REACH OF CHILDREN.**

**CAUTION**

See additional precautionary statements and directions for use in booklet.

**AGRICULTURAL USE REQUIREMENTS**

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. Refer to supplemental labeling under "Agricultural Use Requirements" in the Directions for Use section for information about this standard.

EPA Reg. No. 100-XXXX

EPA Est. XXXXX

Product of XXXXX  
Formulated in XXXXX

SCP

Net Weight

Refer to **FIRST AID** section in attached booklet for additional precautionary statements.

## **PRECAUTIONARY STATEMENTS**

### **Hazards to Humans and Domestic Animals**

#### **CAUTION**

Harmful if swallowed, inhaled, or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Avoid breathing dust or spray mist. Prolonged or frequently repeated exposure may cause allergic skin reactions in some individuals.

This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow drift to blooming crops or weeds if bees are visiting the treatment area.

#### **Physical or Chemical Hazards**

Do not use or store near heat or open flame.

## **STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage and disposal.

### **Pesticide Storage**

Store in a cool, dry area under lock and key. Post as a pesticide storage area. Always store pesticides in the original container. Store away from food, pet food, feed, seed, fertilizers, and veterinary supplies. Place liquid formulations on lower shelves and dry formulations above.

### **Pesticide Disposal**

Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

### **Container Handling**

Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow



begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration.

**Chemigation: Do not apply this product through any type of irrigation system.**

Enfold™ and the SYNGENTA Logo are Trademarks of a Syngenta Group Company.

©2011 Syngenta

Manufactured for:  
Syngenta Crop Protection, LLC  
P.O. Box 18300  
Greensboro, North Carolina 27419-8300

SCP

Enfold (draft new product) – pl – 5/13/11  
000100-XXXXX.20110516.ENFOLD\_NEW-PRODUCT\_MAY2011.pdf

Enfold (draft new product-version b) CLEAN – pl – 9/21/11  
000100-XXXXX.20110921.ENFOLD\_NEW-PRODUCT-B\_SEP2011.pdf



head's up: emamectin ornamental 100-RURR - what analysis needed

Thomas Harris o Dana Spatz, Paula Deschamp

06/14/2011 05:19 PM

Cc: Meredith Laws, Rosanna Louie-Juzwiak

Head's up:

I just received a somewhat odd new product 100-RURR. In lieu of a team meeting, I thought we could discuss how to handle this via email.

This is an e-submission so all material is in Documentum under 100-RURR. This will be the first outdoor foliar use on commercial ornamentals (RUP, no greenhouse, no residential use). The A.I. is currently registered for foliar application to field crops (RUP), as a cockroach bait (RUP professional use crack /crevice), and as a tree injection (RUP). Actually, there's nothing unusual about the proposed product; the issue is how do we review this?

Here's the application letter:



Cover-Enfold-Insecticide\_A10324A-5-17-2011.pdf

Since the CSF is equal to another product there is no prod chem or acute tox (just cite from 100-904). The only data submitted with this application are three environmental fate studies. The registrant seeks to have us reduce the half-life from current 579 days and redo the ground and surface water exposure. But this in turn could affect the dietary risk assessment. We might also want to do an occupational exposure assessment (although I suspect it's similar to field crops; HED can decide).

>>>> What analyses do we need to do for this new product?

I've already sent DPs to HED (DP 390788) and EFED (DP 390789). If you need any other DPs just let me know.

Tom Harris  
EPA/OCSP/OPP/RD/IRB  
voice: (703) 308-9423  
fax: (703) 308-0029  
harris.thomas@epa.gov  
visit <http://www.epa.gov/pesticides>



## Summary Report

| Registration # | Name                                   | Status                                 | Restricted Use Product | Company # | Company Name                  | Percent Active Ingredient | Active Ingredient  |
|----------------|----------------------------------------|----------------------------------------|------------------------|-----------|-------------------------------|---------------------------|--------------------|
| 100-902        | EMAMECTIN BENZOATE TECHNICAL           | Conditionally Registered (19-May-1999) | N                      | 100       | SYNGENTA CROP PROTECTION, LLC | 97                        | Emamectin benzoate |
| 100-903        | DENIM INSECTICIDE                      | Conditionally Registered (19-May-1999) | Y                      | 100       | SYNGENTA CROP PROTECTION, LLC | 2.15                      | Emamectin benzoate |
| 100-904        | PROCLAIM INSECTICIDE                   | Conditionally Registered (19-May-1999) | Y                      | 100       | SYNGENTA CROP PROTECTION, LLC | 5                         | Emamectin benzoate |
| 100-1245       | EMAMECTIN 5SG MG                       | Conditionally Registered (05-Apr-2006) | N                      | 100       | SYNGENTA CROP PROTECTION, LLC | 5                         | Emamectin benzoate |
| 100-1270       | EMAMECTIN BENZOATE TECHNICAL II        | Conditionally Registered (19-Dec-2007) | N                      | 100       | SYNGENTA CROP PROTECTION, LLC | 97                        | Emamectin benzoate |
| 100-1290       | OPTIGARD COCKROACH BAIT                | Conditionally Registered (26-Jun-2008) | N                      | 100       | SYNGENTA CROP PROTECTION, LLC | .1                        | Emamectin benzoate |
| 100-1309       | EMAMECTIN BENZOATE 4.0% TREE INJECTION | Conditionally Registered (11-Jul-2009) | Y                      | 100       | SYNGENTA CROP PROTECTION, LLC | 4                         | Emamectin benzoate |



JACKETS (Fileroom Document Tracking System)  
Requested Jackets Report (New Requests)

13-Jun-2011  
12:24 PM  
Adams, Teretha  
21369  
Page 1 of 1

Requested by : Harris, Thomas

Barcode :

Agency : EPA Office : OSCPP Program : OPP  
Division : RD Branch : IRB

Requested on 13-Jun-2011 at 12:24 PM

Group Num: 241398

| Jacket<br>Barcode | Regulatory<br>Case File # | Vol/Tot | Location                 | Status                     |
|-------------------|---------------------------|---------|--------------------------|----------------------------|
| 9290819           | 100-RURR                  | 1 / 1   | File Rm: 67 / A / 01 / 1 | Under Review (19-May-2011) |

Total # of jackets requested :

1

Completed:

AS

Date:

6/13/11

Time:

12:26pm

**Harris, Thomas**

**21-Day Screen Completed by**  
**Contractor**

**21-Day Expires on** 6-8-11

**Jacket #** 100 - RURR  
**MRID#** 484801

**Content Screen:** Recommend to Pass/Fail

**86-5 Review:** Pass/Fail/NA See Page 3

**Overall Status:** Recommend to Pass/Fail

**Transfer This Jacket to:**

Stephen Schaible

PMI

## To the Document Center (ITRMD)

\*Please transfer jacket/mini-jacket to the Product Manager Team circled below:

Minor Use Section: **PM -5**

Insecticide Branch: **PM -10** **PM-13**

Herbicide Branch: **PM-23** **PM-25**

Fungicide Branch: **PM-20** **PM-21** **PM-22**

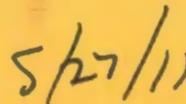
Insect/Rodent Branch: **PM-1** **PM-7**

\*Reminder to PM – If applicable, pick-up data from the Screening Room.

Processed by RD's Completeness Check Team



(Team Member Signature)



(Date)



JACKETS (Fileroom Document Tracking System)  
Requested Jackets Report (New Requests)

27-May-2011  
11:24 AM  
Smith, Angela

Requested by : Eagle, Venus

Barcode : 20512

Agency : EPA Office : OSCPP Program : OPP  
Division : RD Branch : IRB

Page 1 of 1

Requested on 27-May-2011 at 11:24 AM

Group Num: 240152

| Jacket<br>Barcode | Regulatory<br>Case File # | Vol/Tot | Location                 | Status                     |
|-------------------|---------------------------|---------|--------------------------|----------------------------|
| 9290819           | 100-RURR                  | 1 / 1   | File Rm: 67 / A / 01 / 1 | Under Review (19-May-2011) |

Total # of jackets requested :

1

Completed:

*AS*

Date:

*5/27/11*

Time:

*11:30pm*

**Eagle, Venus**

# Completion of 21-Day Content Screen

PM- 7


EPA Reg. # (File Symbol) 100-RURR

Decision # D 449308

Data package delivered to  
you on 5/27/11.  
(date)

Jacket/Mini-jacket will be  
transferred to you today.  
(Pick up from Document Center)

Thank you,



Registration Division's 21-Day Content Team

**Memorandum**

Date: 05 / 25 / 11

To: PM 1, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

**We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.**

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission  
☐ partially accepted submission  
☐ rejected submission





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

May 25, 2011

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

BUNNIE KONAT  
SYNGENTA CROP PROTECTION, LLC  
D/B/A SYNGENTA CROP PROTECTION, INC.  
PO Box 18300  
GREENSBORO, NC 27419-8300

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 18-MAY-11. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



Thomas J. Parshley  
Senior Regulatory Product Manager  
Syngenta Regulatory Affairs  
Professional Products  
(336) 632-7207 (phone)  
(336) 632-5688 (fax)  
tom.parshley@syngenta.com

Syngenta Crop Protection, LLC  
P.O. Box 18300  
Greensboro, NC 27419-8300  
www.syngenta.com

VIA FEDEX / ELECTRONIC SUBMISSION

**CONFIDENTIAL BUSINESS INFORMATION ENCLOSED**

May 17, 2011

Document Processing Desk (E-SUB) (APPL) (REG-FEE)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
2777 South Crystal Drive  
Room S-4900, One Potomac Yard  
Arlington, VA 22202-4501

**Attention:** Mr. Tom Harris, PM Team 1, Insecticide Branch  
Registration Division

**SUBJECT:** APPLICATION FOR NEW PRODUCT REGISTRATION:  
Enfold™ Insecticide, EPA FILE SYMBOL 100-XXXX  
PRIA ACTION CODE R230  
E-SUBMISSION

Dear Mr Harris:

Syngenta herein submits an application for a new end-use product registration for the subject product for use in outdoor field and container ornamentals.

Enfold [Insecticide] is the same formulation as Proclaim Insecticide, EPA Reg. No. 100-xxx, but is for outdoor containerized and field grown ornamentals.

Enclosed please find the following information which is being provided in support of this application for registration for the subject product being filed as an electronic submission:

- PRIA II Category R230 prepayment
- Application for Pesticide Registration (EPA Form 8570-1)
- Two (2) Confidential Statement of Formula (Basic & Alternate) (EPA Form 8570-4)
- PDF version of proposed product labeling
- Two (2) Certification with Respect to Data Citation (EPA Form 8570-34)
- Data matrices for the technical emamectin benzoate as well as for the product specific data (EPA Form 8570-35)
- Transmittal document
- Three (3) Data Volumes: New aerobic soil metabolism studies (see explanation below).

**NEW DATA FOR REFINEMENT OF ECOLOGICAL & DIETARY RISK ASSESSMENTS**

Emamectin benzoate-based end-use products (Proclaim®, Denim®) are registered for a variety of agricultural crop uses. Syngenta is requesting registration for a new Section 3 use for field grown ornamental plants and anticipates that the Agency will evaluate this new use pattern with respect to ground and surface water exposure.

There is currently one accepted emamectin benzoate aerobic soil metabolism study (MRID 43404303); the half-life in this study was 193 days. As per EPA guidance for selecting modeling input parameters (PRZM/EXAMS), when only a single half-life value is available for aerobic soil





Mr. Tom Harris  
May 17, 2011 – E-Sub Application for New Product Registration for Enfold Insecticide  
Page 2 of 2

metabolism the single value should be multiplied by 3; thus, the EPA is presently using a half-life value of 579 days to determine the model input value for emamectin benzoate:

- 193-day half-life from the single aerobic soil metabolism study  $\times 3$  = half-life of 579 days

To refine this half-life value input to the exposure modeling and to provide additional information related to the degradation of emamectin benzoate in the environment, Syngenta is submitting 3 aerobic soil metabolism reports that include 7 additional half-life values. By using a total of 8 half-life values, Syngenta determined the half-life input for exposure modeling could be reduced considerably.

Use of the additional aerobic soil metabolism data will result in more accurate risk assessments for current uses of emamectin benzoate as well as the proposed use on ornamentals.

#### **Fees for Services**

Enfold is the same formulation as Proclaim as noted above. However, the non-food outdoor use for ornamentals is new for emamectin benzoate. Consequently the appropriate PRIA category for this registration is R230, with a 15-month review timeline and a prepaid fee of \$23,969.

If there are any questions concerning matters contained in this submission, please do not hesitate to contact myself at either 336-632-7207 or by e-mail at [tom.parshley@syngenta.com](mailto:tom.parshley@syngenta.com). Also, you may contact my regulatory assistant Pat Eay at 336-632-6746 or by e-mail at [pat.eay@syngenta.com](mailto:pat.eay@syngenta.com).

Sincerely,

Thomas J. Parshley  
Senior Regulatory Product Manager for Lawn and Garden  
Syngenta Crop Protection, LLC

Enclosed information (Forms, transmittal, and data on CD)



**VOLUME 1 OF 4 OF SUBMISSION  
(TRANSMITTAL DOCUMENT)**

**1. Name and Address of Submitter**

Syngenta Crop Protection, LLC  
P.O. Box 18300  
Greensboro, NC 27419

**2. Regulatory Action in Support of which this Package is Submitted**

Application for New Product Registration:  
Enfold Insecticide, EPA File Symbol No. 100-XXXX.

**3. Transmittal Date**

05/17/2011

**4. List of Submitted Studies**

| MRID<br>NUMBER | VOLUME<br>NUMBER | STUDY<br>TITLE                                                                                                                                                                              | EPA GUIDELINE<br>NUMBER |
|----------------|------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|
| 48480100       | 1 OF 4           | Transmittal Document                                                                                                                                                                        | N/A                     |
| 48480101       | 2 OF 4           | Emamectin Benzoate - Aerobic Soil<br>Metabolism of 14C-NOA426007 and 14C-<br>NOA422390, , (423374)                                                                                          | 835.4100                |
| 48480102       | 3 OF 4           | Route and Rate of Degradation of<br>NOA426007 in Three Soils, Under Aerobic<br>Laboratory Conditions, at 20°C, ,<br>(MK244_50274)                                                           | 835.4100                |
| 48480103       | 4 OF 4           | Rate of Degradation of [14C]Emamectin<br>Benzoate B1a (14C-NOA426007) in One<br>Soil Under Various Laboratory Conditions at<br>20°C (Including Addendum to the Report) , ,<br>(MK244_50275) | 835.4100                |

COMPANY OFFICIAL THOMAS J. PARSHLEY  
(NAME)

Thomas J. Parshley  
(SIGNATURE)

COMPANY NAME: SYNGENTA CROP PROTECTION, LLC

COMPANY CONTACT: THOMAS J. PARSHLEY  
(NAME)

(336) 632-7207  
(PHONE)



|                      |
|----------------------|
| Decision Status      |
| Tracking             |
| Create Resubmission  |
| FFS Letters          |
| Waiver Documentation |
| Action Code History  |
| Secondary Decision   |

| Receipts                                                                                  | Staff Member   | Reg/DCI Number | Submission Due Dt | Response            |
|-------------------------------------------------------------------------------------------|----------------|----------------|-------------------|---------------------|
|  S-995205 | Harris, Thomas | ...            | 100-RURR          | 08-Sep-2012 PENDING |

New use application for outdoor field and container ornamentals.

NEW APPLICATIONS

DATE: 5/18/2011

FILE NUMBER: 100-PURR

FEP (OPPIN ENTRY) GM/LV MAY 19 2011  
(Initial & date)

FILE ROOM: \_\_\_\_\_  
(Initial & date)

SIG: \_\_\_\_\_  
(Initial & date)

FILE ROOM: \_\_\_\_\_  
(Initial & date)

✓ ASSIGN TO PM - / (NO DATA)

       JACKET TO SHELF (DATA)

E-SUBMISSION 343





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

April 28, 2011

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

OPP Decision Number: D-447325  
EPA File Symbol or Registration Number: 13283-14  
Product Name: RAINBOW FIRE ANT KILLER  
EPA Application Receipt Date: 04-Apr-2011  
EPA Waiver Request Receipt Date: 04-Apr-2011  
EPA Company Number: 13283  
Company Name: RAINBOW TECHNOLOGY CORPORATION

KIM DAVIS  
REGWEST COMPANY, LLC  
RAINBOW TECHNOLOGY CORPORATION  
8203 WEST 20TH STREET, SUITE A  
GREELEY, CO 80634-4696

SUBJECT: Approval of Waiver Request

Dear Registrant:

The Office of Pesticide Programs has approved your request for 75% waiver of the pesticide registration fee associated with the action referenced above. The decision review period for this action will begin on the date of this letter.

The Action has been identified as Action Code: R340

NON-FAST-TRACK (INCLUDES CHANGES TO PRECAUTIONARY LABEL  
STATEMENTS;SOURCE CHANGES TO AN UNREGISTERED SOURCE);

If you have any questions, please contact the Pesticide Registration Service Fee  
Ombudsman, at (703) 308-9362.

Sincerely,

A handwritten signature in cursive script, appearing to read "Oscar Morales".

Oscar Morales, Director  
Information Technology & Resources Management Division  
Office of Pesticide Programs

# PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 5-18-11

Experts In-Processing Signature: M F HARRINGTON Date 5-20-11 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date                     

| EPA Reg. Number: <u>100 - RURR</u> |                                                                                                                                                                                                                                                                                                                                                                                                       | EPA Receipt Date: <u>5-18-11</u> |    |     |    |      |
|------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----|-----|----|------|
| Items for Review                   |                                                                                                                                                                                                                                                                                                                                                                                                       |                                  |    | Yes | No | N/A* |
| 1                                  | <b>Application Form</b> (EPA Form 8570-1)(link to form) signed & complete including package type                                                                                                                                                                                                                                                                                                      |                                  |    | X   |    |      |
| 2                                  | <b>Confidential Statement of Formula</b> all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)                                                                                                                                                                                                                                                                                 |                                  |    | X   |    |      |
|                                    | a) All inerts (link to <a href="http://www.epa.gov/opprd001/inerts/">http://www.epa.gov/opprd001/inerts/</a> ), including fragrances, approved for the proposed uses (see Footnote A)                                                                                                                                                                                                                 | yes                              | no |     |    |      |
|                                    |                                                                                                                                                                                                                                                                                                                                                                                                       | X                                |    |     |    |      |
| 3                                  | <b>Certification with Respect to Citation of Data</b> (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)                                                                                                                                                                                                                                                                     |                                  |    | X   |    |      |
|                                    | Certificate and data matrix consistent                                                                                                                                                                                                                                                                                                                                                                |                                  |    | X   |    |      |
|                                    | If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)                                                                                                                                                                                                                                                                                        | yes                              | no |     |    |      |
|                                    |                                                                                                                                                                                                                                                                                                                                                                                                       |                                  |    |     |    |      |
|                                    | If applicable, is there a letter of Authorization for exclusive use only.                                                                                                                                                                                                                                                                                                                             |                                  |    |     |    |      |
| 4                                  | <b>Formulator's Exemption Statement</b> (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)                                                                                                                                                                                                                                        |                                  |    |     |    | X    |
|                                    | <b>Data Matrix</b> (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)                                                                                                                                                                                                                                          |                                  |    | X   |    |      |
| 5                                  | a) Selective Method (Fee category experts use)                                                                                                                                                                                                                                                                                                                                                        | yes                              | no |     |    |      |
|                                    |                                                                                                                                                                                                                                                                                                                                                                                                       | X                                |    |     |    |      |
|                                    | b) Cite-All (Fee category experts use)                                                                                                                                                                                                                                                                                                                                                                |                                  |    |     |    |      |
|                                    | c) Applicant owns all data (Fee category experts use)                                                                                                                                                                                                                                                                                                                                                 |                                  |    |     |    |      |
| 6                                  | <b>5 Copies of Label</b> (link to <a href="http://www.epa.gov/oppfead1/labeling/lrm/">http://www.epa.gov/oppfead1/labeling/lrm/</a> ) (Electronic labels on CD are encouraged and guidance is available)( link to <a href="http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels">http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels</a> ) |                                  |    | X   |    |      |

|    |                                                                                                                                                                                                                                                                                                                                              |   |  |   |
|----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|--|---|
| 7  | Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)                                                                                                                                                                                                                                                                        | X |  |   |
| 8  | Notice of Filing (link to <a href="http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm">http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm</a> ) included with petitions (link to <a href="http://www.epa.gov/pesticides/regulating/tolerances.htm">http://www.epa.gov/pesticides/regulating/tolerances.htm</a> ) |   |  | X |
| 9  | If applicable for conventional applications, reduced risk rationale (link to <a href="http://www.epa.gov/opprd001/workplan/reducedrisk.html">http://www.epa.gov/opprd001/workplan/reducedrisk.html</a> )                                                                                                                                     |   |  | X |
| 10 | Required Data (link to <a href="http://www.epa.gov/pesticides/regulating/data_requirements.htm">http://www.epa.gov/pesticides/regulating/data_requirements.htm</a> ) and/or data waivers. See Footnote C.                                                                                                                                    |   |  | X |
|    | a) List study (or studies) not included with application                                                                                                                                                                                                                                                                                     |   |  |   |



Comments:

ILLEGIBILITY ISSUES WITH THE STUDIES SUBMITTED. SINCE IT IS AN RESUBMISSION, THE REGISTRANT HAS AGREED TO SEND AN ELECTRONIC VERSION OF THE CORRECTED STUDY TO G. MCCANN. THE JACKET PASSES, AND THE 86-5 PROCESS WILL CONTINUE IN OPPIN AS A FULLY ACCEPTED SUBMISSION. STUDY IS MARKED AS "FAIL" IN DOCUMENTUM. AA 5/24/11

NON-FOOD USE PRODUCT

MRID 484801

\* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/opprd001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at [inertsbranch@epa.gov](mailto:inertsbranch@epa.gov) and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to [http://www.epa.gov/oppbppd1/biopesticides/contacts\\_bppd.htm](http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm)].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/opprd001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

### **Unapproved Inerts Identified on CSFs**

#### **All applications except conventional new products and PIPs**

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;



3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

#### Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

#### PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.



3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



**FW: Regarding Application for Registration of 100-RURR**

**pat.eay** to: Anthony Ashe

Cc: tom.parshley

05/24/2011 10:19 AM

Good Morning Anthony,

Thank you for your email referencing a deficiency associated with our submission in support of our Application for Registration for Enfold Insecticide, EPA File Symbol No. 100-RURR, and the deficiencies in our study assigned to MRID 48480103.

We are currently addressing to correct this deficiency and will be resubmitting the revised study this week. A full and revised version will be provided electronically on CD and will be FedEx to Ms. Geri McCann and Teresa Downs as stated below.

We thank you for bringing this to our attention and we apologize for all the inconveniences.

Best Regards,

Pat Eay  
Administrative Assistant  
Syngenta Crop Protection, Inc.  
P.O. Box 18300  
Greensboro, NC 27419  
336-632-6746  
336-632-5688 Fax

-----Original Message-----

From: Ashe.Anthony@epamail.epa.gov [mailto:Ashe.Anthony@epamail.epa.gov]

Sent: Tuesday, May 24, 2011 9:07 AM

To: Parshley Tom USGR; Eay Pat USGR

Subject: Regarding Application for Registration of 100-RURR

Hello,

This message is being sent regarding deficiencies in one of the studies submitted. These issues require attention before the application process can be completed. In volume 4 (MRID 48480103), pages 58, 98, 100, 124, 124, 125, 132, and 137 have illegible portions. Please make your best attempt to deliver a clear copy, but if the copy submitted is the best available, please mark it as such (with a stamp or a signed "best available copy" statement) and resubmit. Because your studies were submitted electronically, a full and revised version of only that study should be resubmitted through the same process, to the attention of Geri McCann and Teresa Downs. Additionally, please inform me of your intent to resolve these issues, so I can move the application process forward in as timely a manner as possible. Feel free to contact me with any questions, and thank you for your attention to this matter.

Anthony H Ashe  
MacFadden Contractor  
(703)305-0073

any copies. Any use of the message by you is prohibited.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

May 20, 2011

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

OPP Decision Number: D-449308  
EPA File Symbol or Registration Number: 100-RURR  
Product Name: Enamectin Benzoate  
EPA Receipt Date: 18-May-2011  
EPA Company Number: 100  
Company Name: SYNGENTA CROP PROTECTION, LLC

BUNNIE KONAT  
SYNGENTA CROP PROTECTION, LLC  
D/B/A SYNGENTA CROP PROTECTION, INC.  
PO Box 18300  
GREENSBORO, NC 27419-8300

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R230

NEW USE;OUTDOOR;NON-FOOD;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "m. j. h.", is written over the printed name of the staff member.

Front End Processing Staff  
Information Technology & Resources Management Division

# Fee for Service

{896205&~

This package includes the following

☒ New Registration

☐ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: \_\_\_\_

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr.

Receipt No.

S-

EPA File Symbol/Reg. No.

Pin-Punch Date:

☐ This item is NOT subject to FFS action.

## Action Code:

Requested:

Granted:

Amount Due: \$ 23,965.<sup>00</sup>

## Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: AGS

Date: 5-20-11

Remarks:



# Receipt for Section 3

S: 896205

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 100 SYNGENTA CROP PROTECTION, LLC



Risk Manager: Registration Division, Risk Management Team 1

Product #: 100-RURR

Product Name: Enamectin Benzoate

Override#

Me Too  
Section3:

Me Too  
Product Name:

Application Date: 17-May-2011



OPP Rec'd Date: 18-May-2011



Front End Date: 19-May-2011



Risk Manager Send Date:



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

| Receipt Content |  |
|-----------------|--|
| Study           |  |
| CSF             |  |

Fast Track: ☐

New Ingredient: ☐

View/Edit

Receipt Description:

Associated with e-Submission package #2272. Application for registration.

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:



**From:** [paygovadmin@mail.doc.twal.gov](mailto:paygovadmin@mail.doc.twal.gov)  
**To:** [Eav Pat USGR](#)  
**Subject:** Pay.Gov Payment Confirmation  
**Date:** Friday, May 13, 2011 3:17:08 PM

---

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Your transaction has been successfully completed.

Transaction Summary

Application Name: PRIA Service Fees  
Pay.gov Tracking ID: 253BO9FB  
Agency Tracking ID: 74201179628  
Transaction Type: Sale  
Transaction Date: May 13, 2011 3:16:56 PM

5-17-2011 Tom Parshely  
ENFOLD Insecticide 100-xxxx  
Emamectin Benzoate  
Use in Outdoor Field and Container  
Ornamentals  
R230, 15 months, \$23,969

Account Holder Name: Janis McFarland  
Transaction Amount: \$23,969.00  
Billing Address: P.O. Box 18300  
City: Greensboro  
State/Province: NC  
Zip/Postal Code: 27419  
Country: USA  
Card Type: Visa  
Card Number: \*\*\*\*\*6187

Decision Number:  
Registration Number: 100-xxxx  
Company Name: Syngenta Crop Protection  
Company Number: 100  
Action Code: R230

**E-SUBMISSION**



Thomas J. Parshley  
Senior Regulatory Product Manager  
Syngenta Regulatory Affairs  
Professional Products  
(336) 632-7207 (phone)  
(336) 632-5688 (fax)  
tom.parshley@syngenta.com

Syngenta Crop Protection, LLC  
P.O. Box 18300  
Greensboro, NC 27419-8300  
www.syngenta.com

VIA FEDEX / ELECTRONIC SUBMISSION

**CONFIDENTIAL BUSINESS INFORMATION ENCLOSED**

May 17, 2011

Document Processing Desk (E-SUB) (APPL) (REG-FEE)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
2777 South Crystal Drive  
Room S-4900, One Potomac Yard  
Arlington, VA 22202-4501

**Attention:** Mr. Tom Harris, PM Team 1, Insecticide Branch  
Registration Division

**SUBJECT:** APPLICATION FOR NEW PRODUCT REGISTRATION:  
Enfold™ Insecticide, EPA FILE SYMBOL 100-XXXX  
PRIA ACTION CODE R230  
E-SUBMISSION

*RuRr*

Dear Mr Harris:

Syngenta herein submits an application for a new end-use product registration for the subject product for use in outdoor field and container ornamentals.

Enfold [Insecticide] is the same formulation as Proclaim Insecticide, EPA Reg. No. 100-xxx, but is for outdoor containerized and field grown ornamentals.

*-904*

Enclosed please find the following information which is being provided in support of this application for registration for the subject product being filed as an electronic submission:

- PRIA II Category R230 prepayment
- Application for Pesticide Registration (EPA Form 8570-1)
- Two (2) Confidential Statement of Formula (Basic & Alternate) (EPA Form 8570-4)
- PDF version of proposed product labeling
- Two (2) Certification with Respect to Data Citation (EPA Form 8570-34)
- Data matrices for the technical emamectin benzoate as well as for the product specific data (EPA Form 8570-35)
- Transmittal document
- Three (3) Data Volumes: New aerobic soil metabolism studies (see explanation below).

**NEW DATA FOR REFINEMENT OF ECOLOGICAL & DIETARY RISK ASSESSMENTS**

Emamectin benzoate-based end-use products (Proclaim®, Denim®) are registered for a variety of agricultural crop uses. Syngenta is requesting registration for a new Section 3 use for field grown ornamental plants and anticipates that the Agency will evaluate this new use pattern with respect to ground and surface water exposure.

There is currently one accepted emamectin benzoate aerobic soil metabolism study (MRID 43404303); the half-life in this study was 193 days. As per EPA guidance for selecting modeling input parameters (PRZM/EXAMS), when only a single half-life value is available for aerobic soil

**E-SUBMISSION**





Mr. Tom Harris  
May 17, 2011 – E-Sub Application for New Product Registration for Enfold Insecticide  
Page 2 of 2

metabolism the single value should be multiplied by 3; thus, the EPA is presently using a half-life value of 579 days to determine the model input value for emamectin benzoate:

- 193-day half-life from the single aerobic soil metabolism study x 3 = half-life of 579 days

To refine this half-life value input to the exposure modeling and to provide additional information related to the degradation of emamectin benzoate in the environment, Syngenta is submitting 3 aerobic soil metabolism reports that include 7 additional half-life values. By using a total of 8 half-life values, Syngenta determined the half-life input for exposure modeling could be reduced considerably.

Use of the additional aerobic soil metabolism data will result in more accurate risk assessments for current uses of emamectin benzoate as well as the proposed use on ornamentals.

#### **Fees for Services**

Enfold is the same formulation as Proclaim as noted above. However, the non-food outdoor use for ornamentals is new for emamectin benzoate. Consequently the appropriate PRIA category for this registration is R230, with a 15-month review timeline and a prepaid fee of \$23,969.

If there are any questions concerning matters contained in this submission, please do not hesitate to contact myself at either 336-632-7207 or by e-mail at [tom.parshley@syngenta.com](mailto:tom.parshley@syngenta.com). Also, you may contact my regulatory assistant Pat Eay at 336-632-6746 or by e-mail at [pat.eay@syngenta.com](mailto:pat.eay@syngenta.com).


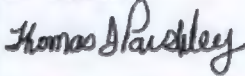
Sincerely,

A handwritten signature in black ink that reads "Thomas J. Parshley".

Thomas J. Parshley  
Senior Regulatory Product Manager for Lawn and Garden  
Syngenta Crop Protection, LLC

Enclosed information (Forms, transmittal, and data on CD)



|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                 |                                                                                                                                                                                                 |                                                                                                                                                                                                                                                 |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  <b>United States</b><br><b>Environmental Protection Agency</b><br>Washington, DC 20460                                                                                                                                                                                                                                                                                                                                                   |                                                                                                 | <input checked="checked" type="checkbox"/> <b>Registration</b><br><input type="checkbox"/> <b>Amendment</b><br><input type="checkbox"/> <b>Other</b>                                            | OPP Identifier Number                                                                                                                                                                                                                           |
| <b>Application for Pesticide - Section I</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                 |                                                                                                                                                                                                 |                                                                                                                                                                                                                                                 |
| 1. Company/Product Number<br>100-XXXX <b>RURR</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                 | 2. EPA Product Manager<br>Mr. Tom Harris                                                                                                                                                        |                                                                                                                                                                                                                                                 |
| 4. Company/Product (Name)<br>Enfold™ Insecticide                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                 | 3. Proposed Classification<br><input type="checkbox"/> None <input checked="checked" type="checkbox"/> Restricted                                                                               |                                                                                                                                                                                                                                                 |
| 5. Name and Address of Applicant (Include ZIP Code)<br>Syngenta Crop Protection, LLC<br>P. O. Box 18300<br>Greensboro, NC 27419<br><br><input type="checkbox"/> Check if this is a new address                                                                                                                                                                                                                                                                                                                             |                                                                                                 | 6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:<br><br>EPA Reg. No. _____<br>Product Name _____ |                                                                                                                                                                                                                                                 |
| <b>Section - II</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                 |                                                                                                                                                                                                 |                                                                                                                                                                                                                                                 |
| <input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Final printed labels in response to Agency letter dated _____<br><input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application.<br><input type="checkbox"/> Notification - Explain below. <input checked="checked" type="checkbox"/> Other - Explain below.                                                                                                                    |                                                                                                 |                                                                                                                                                                                                 |                                                                                                                                                                                                                                                 |
| <b>Explanation:</b> Use additional page(s) if necessary. (For Section I and Section II)<br><br>Application for New Product Registration for Enfold™ Insecticide for use in outdoor field and container ornamentals. In compliance with the Pesticide Registration Improvement Act, Syngenta Crop Protection has paid the required pesticide registration fee for this action. Syngenta believes that this application qualifies as a PRIA II R230 action with a 15-month timeline and a fee of \$23,969 which is enclosed. |                                                                                                 |                                                                                                                                                                                                 |                                                                                                                                                                                                                                                 |
| <b>Section - III</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                 |                                                                                                                                                                                                 |                                                                                                                                                                                                                                                 |
| 1. <b>Material This Product Will Be Packaged In:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                 |                                                                                                                                                                                                 |                                                                                                                                                                                                                                                 |
| Child-Resistant Packaging<br><input type="checkbox"/> Yes*<br><input type="checkbox"/> No                                                                                                                                                                                                                                                                                                                                                                                                                                  | Unit Packaging<br><input type="checkbox"/> Yes<br><input checked="checked" type="checkbox"/> No | Water Soluble Packaging<br><input type="checkbox"/> Yes<br><input checked="checked" type="checkbox"/> No                                                                                        | 2. Type of Container<br><input type="checkbox"/> Metal<br><input checked="checked" type="checkbox"/> Plastic<br><input type="checkbox"/> Glass<br><input type="checkbox"/> Paper<br><input type="checkbox"/> Other (Specify) Plastic tube _____ |
| *Certification must<br>If "Yes"      No. per<br>Unit Packaging wgt.      Container                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                 | If "Yes"      No. per<br>Unit Packaging wgt.      container                                                                                                                                     |                                                                                                                                                                                                                                                 |
| 3. Location of Net Contents Information<br><input checked="checked" type="checkbox"/> Label <input type="checkbox"/> Container                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                 | 4. Size(s) Retail Container<br>1.21 lb. (19.2 oz.) and 1.4 lb. (22.5 oz.)                                                                                                                       |                                                                                                                                                                                                                                                 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                 | 5. Location of Label Directions<br><input checked="checked" type="checkbox"/> On Label<br><input type="checkbox"/> On Labeling accompanying product                                             |                                                                                                                                                                                                                                                 |
| 6. Manner in Which Label is Affixed to Product<br><input type="checkbox"/> Lithograph <input checked="checked" type="checkbox"/> Outer box is preprinted _____<br><input type="checkbox"/> Paper glued for tubes<br><input type="checkbox"/> Stenciled                                                                                                                                                                                                                                                                     |                                                                                                 |                                                                                                                                                                                                 |                                                                                                                                                                                                                                                 |
| <b>Section - IV</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                 |                                                                                                                                                                                                 |                                                                                                                                                                                                                                                 |
| 1. <b>Contact Point</b> (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                 |                                                                                                                                                                                                 |                                                                                                                                                                                                                                                 |
| Name<br>Thomas J. Parshley                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                 | Title<br>Senior Reg. Product Manager                                                                                                                                                            |                                                                                                                                                                                                                                                 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                 | Telephone No. (Include Area Code)<br>336-632-7207                                                                                                                                               |                                                                                                                                                                                                                                                 |
| <b>Certification</b><br>I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.                                                                                                                                                                                                                                         |                                                                                                 |                                                                                                                                                                                                 | 6. Date Application Received (Stamped)                                                                                                                                                                                                          |
| 2. Signature<br>                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                 | 3. Title<br>Regulatory Product Manager, Lawn & Gardens                                                                                                                                          |                                                                                                                                                                                                                                                 |
| 4. Typed Name<br>Thomas J. Parshley                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                 | 5. Date<br>May 17, 2011                                                                                                                                                                         |                                                                                                                                                                                                                                                 |

**VOLUME 1 OF 4 OF SUBMISSION  
(TRANSMITTAL DOCUMENT)**

**1. Name and Address of Submitter**

Syngenta Crop Protection, LLC  
P.O. Box 18300  
Greensboro, NC 27419

**2. Regulatory Action in Support of which this Package is Submitted**

Application for New Product Registration:  
Enfold Insecticide, EPA File Symbol No. 100-XXXX.

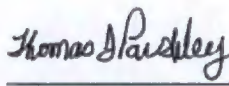
**3. Transmittal Date**

05/17/2011

**4. List of Submitted Studies**

| MRID<br>NUMBER | VOLUME<br>NUMBER | STUDY<br>TITLE                                                                                                                                                                              | EPA GUIDELINE<br>NUMBER |
|----------------|------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|
| 48480100       | 1 OF 4           | Transmittal Document                                                                                                                                                                        | N/A                     |
| 48480101       | 2 OF 4           | Emamectin Benzoate - Aerobic Soil<br>Metabolism of 14C-NOA426007 and 14C-<br>NOA422390, , (423374)                                                                                          | 835.4100                |
| 48480102       | 3 OF 4           | Route and Rate of Degradation of<br>NOA426007 in Three Soils, Under Aerobic<br>Laboratory Conditions, at 20°C, ,<br>(MK244_50274)                                                           | 835.4100                |
| 48480103       | 4 OF 4           | Rate of Degradation of [14C]Emamectin<br>Benzoate B1a (14C-NOA426007) in One<br>Soil Under Various Laboratory Conditions at<br>20°C (Including Addendum to the Report) , ,<br>(MK244_50275) | 835.4100                |

COMPANY OFFICIAL THOMAS J. PARSHLEY  
(NAME)

  
(SIGNATURE)

COMPANY NAME: SYNGENTA CROP PROTECTION, LLC

COMPANY CONTACT: THOMAS J. PARSHLEY  
(NAME)

(336) 632-7207  
(PHONE)





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M STREET, S.W.

WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

## Certification with Respect to Citation of Data

|                                                                                                                              |                                                 |
|------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| Applicant's/Registrant's Name, Address, and Telephone Number<br>Syngenta Crop Protection, PO Box 18300, Greensboro, NC 27419 | EPA Registration Number/File Symbol<br>100-1270 |
| Active Ingredient(s) and/or representative test compound(s)<br>Emamectin Benzoate                                            | Date<br>May 17, 2011                            |
| General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)<br>Terrestrial Uses                   | Product Name<br>Emamectin Benzoate Technical    |

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-in Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

## SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

## SECTION II: GENERAL OFFER TO PAY

(Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements)

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application to the extent required by FIFRA.

## SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

|                                        |                   |                                                                                                                        |
|----------------------------------------|-------------------|------------------------------------------------------------------------------------------------------------------------|
| Signature<br><i>Thomas D. Parshley</i> | Date<br>5-17-2011 | Typed or Printed Name and Title<br>Thomas Parshley, Senior Regulatory Manager<br>Professional Products – Lawn & Garden |
|----------------------------------------|-------------------|------------------------------------------------------------------------------------------------------------------------|

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

E-SUBMISSION





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M STREET, S.W.

WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

## Certification with Respect to Citation of Data

|                                                                                                                              |                                                 |
|------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| Applicant's/Registrant's Name, Address, and Telephone Number<br>Syngenta Crop Protection, PO Box 18300, Greensboro, NC 27419 | EPA Registration Number/File Symbol<br>100-XXXX |
| Active Ingredient(s) and/or representative test compound(s)<br>Emamectin Benzoate                                            | Date<br>May 17, 2011                            |
| General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)<br>Terrestrial Uses                   | Product Name<br>ENFOLD INSECTICIDE              |

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-in Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

## SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

## SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application to the extent required by FIFRA.

## SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

|                                     |                   |                                                                                                                        |
|-------------------------------------|-------------------|------------------------------------------------------------------------------------------------------------------------|
| Signature<br><i>Thomas Parshley</i> | Date<br>5-17-2011 | Typed or Printed Name and Title<br>Thomas Parshley, Senior Regulatory Manager<br>Professional Products – Lawn & Garden |
|-------------------------------------|-------------------|------------------------------------------------------------------------------------------------------------------------|

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

# E-SUBMISSION





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street  
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 1 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name                                                 | MRID          | Submitter         | Status | Notes |
|----------------------------|------------------------------------------------------|---------------|-------------------|--------|-------|
| Cite-All                   | Cite-All                                             | Cite-All (AHE | AGRICULTURAL HAN  | PER    |       |
| Cite-All                   | Cite-All                                             | Cite-All (ART | AGRICULTURAL REE  | PER    |       |
| Cite-All                   | Cite-All                                             | Cite-All (FES | FIFRA ENDANGERED  | PER    |       |
| Cite-All                   | Cite-All                                             | Cite-All (ORE | OUTDOOR RESIDENT  | PER    |       |
| Cite-All                   | Cite-All                                             | Cite-All (REJ | RESIDENTIAL EXPOS | PER    |       |
| Cite-All                   | Cite-All                                             | Cite-All (SDT | SPRAY DRIFT TF    | PER    |       |
| 830.1550                   | Product identity and composition                     | 47002101      | SYNGENTA          | OWN    |       |
| 830.1550                   | Product identity and composition                     | 47002102      | SYNGENTA          | OWN    |       |
| 830.1600                   | Description of materials used to produce the product | 47002102      | SYNGENTA          | OWN    |       |
| 830.1620                   | Description of production process                    | 47002102      | SYNGENTA          | OWN    |       |
| 830.1670                   | Discussion of formation of impurities                | 47002102      | SYNGENTA          | OWN    |       |
| 830.1700                   | Preliminary analysis                                 | 47002101      | SYNGENTA          | OWN    |       |

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 2 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name                                                   | MRID     | Submitter | Status | Notes |
|----------------------------|--------------------------------------------------------|----------|-----------|--------|-------|
| 830.1700                   | Preliminary analysis                                   | 47002102 | SYNGENTA  | OWN    |       |
| 830.1750                   | Certified limits                                       | 47002102 | SYNGENTA  | OWN    |       |
| 830.1800                   | Enforcement analytical method                          | 47002102 | SYNGENTA  | OWN    |       |
| 830.6302                   | Color                                                  | 47002103 | SYNGENTA  | OWN    |       |
| 830.6303                   | Physical state                                         | 47002103 | SYNGENTA  | OWN    |       |
| 830.6304                   | Odor                                                   | 47002103 | SYNGENTA  | OWN    |       |
| 830.6313                   | Stability to normal and elevated temperatures, metals, | 47002103 | SYNGENTA  | OWN    |       |
| 830.6314                   | Oxidation/reduction: chemical incompatibility          | 47002103 | SYNGENTA  | OWN    |       |
| 830.6315                   | Flammability                                           | 47002103 | SYNGENTA  | OWN    |       |
| 830.6316                   | Explosability                                          | 47002103 | SYNGENTA  | OWN    |       |
| 830.6317                   | Storage Stability                                      | 47002103 | SYNGENTA  | OWN    |       |
| 830.6319                   | Miscibility                                            | 47002103 | SYNGENTA  | OWN    |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

| Date: 5/16/2011                                                |                                                          | Reg. No: 100-1270                        |           | Page 3 of 24 |       |
|----------------------------------------------------------------|----------------------------------------------------------|------------------------------------------|-----------|--------------|-------|
| Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419 |                                                          | Product: EMAMECTIN BENZOATE TECHNICAL II |           |              |       |
| Ingredient: Emamectin Benzoate                                 |                                                          |                                          |           |              |       |
| Guideline Reference Number                                     | Name                                                     | MRID                                     | Submitter | Status       | Notes |
| 830.6320                                                       | Corrosion characteristics                                | 47002103                                 | SYNGENTA  | OWN          |       |
| 830.6321                                                       | Dielectric breakdown voltage                             | 47002103                                 | SYNGENTA  | OWN          |       |
| 830.7000                                                       | pH                                                       | 47002103                                 | SYNGENTA  | OWN          |       |
| 830.7050                                                       | UV/Visible absorption                                    | 47002103                                 | SYNGENTA  | OWN          |       |
| 830.7100                                                       | Viscosity                                                | 47002103                                 | SYNGENTA  | OWN          |       |
| 830.7200                                                       | Melting point/melting range                              | 47002103                                 | SYNGENTA  | OWN          |       |
| 830.7220                                                       | Boiling point/boiling range                              | 47002103                                 | SYNGENTA  | OWN          |       |
| 830.7300                                                       | Density/relative density/bulk density                    | 47002103                                 | SYNGENTA  | OWN          |       |
| 830.7370                                                       | Dissociation constants in water                          | 47002103                                 | SYNGENTA  | OWN          |       |
| 830.7550                                                       | Partition coefficient (n-octanol/water), shake flask met | 47002103                                 | SYNGENTA  | OWN          |       |
| 830.7840                                                       | Water salubility: column elution method, shake flask     | 47002103                                 | SYNGENTA  | OWN          |       |
| 830.7950                                                       | Water solubility, Vapor pressure                         | 47002103                                 | SYNGENTA  | OWN          |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 4 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name                      | MRID     | Submitter | Status | Notes |
|----------------------------|---------------------------|----------|-----------|--------|-------|
| 850 Series                 | Ecological Effects        | 47767401 | SYNGENTA  | OWN    |       |
| 870.1100                   | Acute oral toxicity       | 47002104 | SYNGENTA  | OWN    |       |
| 870.1100                   | Acute oral toxicity       | 47002105 | SYNGENTA  | OWN    |       |
| 870.1100                   | Acute oral toxicity       | 47153906 | SYNGENTA  | OWN    |       |
| 870.1100                   | Acute oral toxicity       | 47153907 | SYNGENTA  | OWN    |       |
| 870.1100                   | Acute oral toxicity       | 47309303 | SYNGENTA  | OWN    |       |
| 870.1200                   | Acute dermal toxicity     | 47002106 | SYNGENTA  | OWN    |       |
| 870.1200                   | Acute dermal toxicity     | 47153907 | SYNGENTA  | OWN    |       |
| 870.1200                   | Acute dermal toxicity     | 47153908 | SYNGENTA  | OWN    |       |
| 870.1200                   | Acute dermal toxicity     | 47309304 | SYNGENTA  | OWN    |       |
| 870.1300                   | Acute inhalation toxicity | 47002107 | SYNGENTA  | OWN    |       |
| 870.1300                   | Acute inhalation toxicity | 47153907 | SYNGENTA  | OWN    |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street  
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 5 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name                      | MRID     | Submitter | Status | Notes |
|----------------------------|---------------------------|----------|-----------|--------|-------|
| 870.1300                   | Acute inhalation toxicity | 47309305 | SYNGENTA  | OWN    |       |
| 870.2400                   | Acute eye irritation      | 47002108 | SYNGENTA  | OWN    |       |
| 870.2400                   | Acute eye irritation      | 47153907 | SYNGENTA  | OWN    |       |
| 870.2400                   | Acute eye irritation      | 47153909 | SYNGENTA  | OWN    |       |
| 870.2400                   | Acute eye irritation      | 47309306 | SYNGENTA  | OWN    |       |
| 870.2500                   | Acute dermal irritation   | 47002109 | SYNGENTA  | OWN    |       |
| 870.2500                   | Acute dermal irritation   | 47153907 | SYNGENTA  | OWN    |       |
| 870.2500                   | Acute dermal irritation   | 47153910 | SYNGENTA  | OWN    |       |
| 870.2500                   | Acute dermal irritation   | 47309307 | SYNGENTA  | OWN    |       |
| 870.2600                   | Skin sensitization        | 47002110 | SYNGENTA  | OWN    |       |
| 870.2600                   | Skin sensitization        | 47153907 | SYNGENTA  | OWN    |       |
| 870.2600                   | Skin sensitization        | 47153911 | SYNGENTA  | OWN    |       |

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 6 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name                                        | MRID     | Submitter         | Status | Notes |
|----------------------------|---------------------------------------------|----------|-------------------|--------|-------|
| 870.2600                   | Skin sensitization                          | 47309308 | SYNGENTA          | OWN    |       |
| 870.3100                   | 90-Day oral toxicity                        | 42743620 | MERCK & CO., INC. | OWN    |       |
| 870.3100                   | 90-Day oral toxicity                        | 42743621 | MERCK & CO., INC. | OWN    |       |
| 870.3100                   | 90-Day oral toxicity                        | 42743622 | MERCK & CO., INC. | OWN    |       |
| 870.3100                   | 90-Day oral toxicity                        | 42743623 | MERCK & CO., INC. | OWN    |       |
| 870.3100                   | 90-Day oral toxicity                        | 42794201 | MERCK & CO., INC. | OWN    |       |
| 870.3100                   | 90-Day oral toxicity                        | 43868103 | MERCK & CO., INC. | OWN    |       |
| 870.3150                   | Subchronic nonrodent oral toxicity - 90-day | 42743620 | MERCK & CO., INC. | OWN    |       |
| 870.3150                   | Subchronic nonrodent oral toxicity - 90-day | 42743621 | MERCK & CO., INC. | OWN    |       |
| 870.3150                   | Subchronic nonrodent oral toxicity - 90-day | 42743622 | MERCK & CO., INC. | OWN    |       |
| 870.3150                   | Subchronic nonrodent oral toxicity - 90-day | 42743623 | MERCK & CO., INC. | OWN    |       |
| 870.3150                   | Subchronic nonrodent oral toxicity - 90-day | 42794201 | MERCK & CO., INC. | OWN    |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





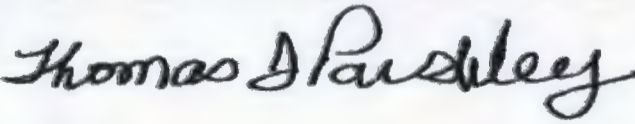
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

| Date: 5/16/2011                                                |                                             | Reg. No: 100-1270                        |                   | Page 7 of 24 |       |
|----------------------------------------------------------------|---------------------------------------------|------------------------------------------|-------------------|--------------|-------|
| Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419 |                                             | Product: EMAMECTIN BENZOATE TECHNICAL II |                   |              |       |
| Ingredient: Emamectin Benzoate                                 |                                             |                                          |                   |              |       |
| Guideline Reference Number                                     | Name                                        | MRID                                     | Submitter         | Status       | Notes |
| 870.3150                                                       | Subchronic nonrodent oral toxicity - 90-day | 43868103                                 | MERCK & CO., INC. | OWN          |       |
| 870.3200                                                       | Repeated dose dermal toxicity - 21/28 day   | 42743625                                 | MERCK & CO., INC. | OWN          |       |
| 870.3200                                                       | Repeated dose dermal toxicity - 21/28 day   | 44007902                                 | MERCK & CO., INC. | OWN          |       |
| 870.3700                                                       | Prenatal developmental toxicity study       | 42743631                                 | MERCK & CO., INC. | OWN          |       |
| 870.3700                                                       | Prenatal developmental toxicity study       | 42743632                                 | MERCK & CO., INC. | OWN          |       |
| 870.3700                                                       | Prenatal developmental toxicity study       | 42743634                                 | MERCK & CO., INC. | OWN          |       |
| 870.3700                                                       | Prenatal developmental toxicity study       | 42743635                                 | MERCK & CO., INC. | OWN          |       |
| 870.3700                                                       | Prenatal developmental toxicity study       | 42743636                                 | MERCK & CO., INC. | OWN          |       |
| 870.3800                                                       | Reproduction and fertility effects          | 42743633                                 | MERCK & CO., INC. | OWN          |       |
| 870.3800                                                       | Reproduction and fertility effects          | 42851511                                 | MERCK & CO., INC. | OWN          |       |
| 870.4100                                                       | Chronic toxicity                            | 42743624                                 | MERCK & CO., INC. | OWN          |       |
| 870.4100                                                       | Chronic toxicity                            | 42851510                                 | MERCK & CO., INC. | OWN          |       |

|                                                                                                                                                    |                 |
|----------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| <br>Thomas J. Parshley, NAFTA Senior Regulatory Product Manager | Date: 5/16/2011 |
|----------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 8 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name                   | MRID     | Submitter         | Status | Notes |
|----------------------------|------------------------|----------|-------------------|--------|-------|
| 870.4100                   | Chronic toxicity       | 42868902 | MERCK & CO., INC. | OWN    |       |
| 870.4100                   | Chronic toxicity       | 43868104 | MERCK & CO., INC. | OWN    |       |
| 870.4200                   | Carcinogenicity        | 43868104 | MERCK & CO., INC. | OWN    |       |
| 870.4200                   | Carcinogenicity        | 43868105 | MERCK & CO., INC. | OWN    |       |
| 870.5000                   | Genetic Toxicity tests | 42743637 | MERCK & CO., INC. | OWN    |       |
| 870.5000                   | Genetic Toxicity tests | 42743638 | MERCK & CO., INC. | OWN    |       |
| 870.5000                   | Genetic Toxicity tests | 42743639 | MERCK & CO., INC. | OWN    |       |
| 870.5000                   | Genetic Toxicity tests | 42851512 | MERCK & CO., INC. | OWN    |       |
| 870.5000                   | Genetic Toxicity tests | 42851513 | MERCK & CO., INC. | OWN    |       |
| 870.5000                   | Genetic Toxicity tests | 42851514 | MERCK & CO., INC. | OWN    |       |
| 870.5000                   | Genetic Toxicity tests | 42851515 | MERCK & CO., INC. | OWN    |       |
| 870.5000                   | Genetic Toxicity tests | 42851516 | MERCK & CO., INC. | OWN    |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street  
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 9 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name                                                | MRID     | Submitter         | Status | Notes |
|----------------------------|-----------------------------------------------------|----------|-------------------|--------|-------|
| 870.5000                   | Genetic Toxicity tests                              | 42851517 | MERCK & CO., INC. | OWN    |       |
| 870.5100                   | Bacterial reverse mutation test                     | 47002111 | SYNGENTA          | OWN    |       |
| 870.6100                   | Acute and 28-day delayed neurotoxicity of organopho | 42743611 | MERCK & CO., INC. | OWN    |       |
| 870.6100                   | Acute and 28-day delayed neurotoxicity of organopho | 42743614 | MERCK & CO., INC. | OWN    |       |
| 870.6100                   | Acute and 28-day delayed neurotoxicity of organopho | 42743626 | MERCK & CO., INC. | OWN    |       |
| 870.6100                   | Acute and 28-day delayed neurotoxicity of organopho | 42743627 | MERCK & CO., INC. | OWN    |       |
| 870.6200                   | Neurotoxicity screening battery                     | 42743618 | MERCK & CO., INC. | OWN    |       |
| 870.6200                   | Neurotoxicity screening battery                     | 42743619 | MERCK & CO., INC. | OWN    |       |
| 870.6200                   | Neurotoxicity screening battery                     | 42743624 | MERCK & CO., INC. | OWN    |       |
| 870.6200                   | Neurotoxicity screening battery                     | 42743628 | MERCK & CO., INC. | OWN    |       |
| 870.6200                   | Neurotoxicity screening battery                     | 42743629 | MERCK & CO., INC. | OWN    |       |
| 870.6200                   | Neurotoxicity screening battery                     | 42743630 | MERCK & CO., INC. | OWN    |       |

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

| Date: 5/16/2011                                                |                                 | Reg. No: 100-1270                        |                   | Page 10 of 24 |       |
|----------------------------------------------------------------|---------------------------------|------------------------------------------|-------------------|---------------|-------|
| Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419 |                                 | Product: EMAMECTIN BENZOATE TECHNICAL II |                   |               |       |
| Ingredient: Emamectin Benzoate                                 |                                 |                                          |                   |               |       |
| Guideline Reference Number                                     | Name                            | MRID                                     | Submitter         | Status        | Notes |
| 870.6200                                                       | Neurotoxicity screening battery | 42851503                                 | MERCK & CO., INC. | OWN           |       |
| 870.6200                                                       | Neurotoxicity screening battery | 42851504                                 | MERCK & CO., INC. | OWN           |       |
| 870.6200                                                       | Neurotoxicity screening battery | 42851505                                 | MERCK & CO., INC. | OWN           |       |
| 870.6200                                                       | Neurotoxicity screening battery | 42851506                                 | MERCK & CO., INC. | OWN           |       |
| 870.6200                                                       | Neurotoxicity screening battery | 42851507                                 | MERCK & CO., INC. | OWN           |       |
| 870.6200                                                       | Neurotoxicity screening battery | 42851508                                 | MERCK & CO., INC. | OWN           |       |
| 870.6200                                                       | Neurotoxicity screening battery | 42851509                                 | MERCK & CO., INC. | OWN           |       |
| 870.6200                                                       | Neurotoxicity screening battery | 42851510                                 | MERCK & CO., INC. | OWN           |       |
| 870.6200                                                       | Neurotoxicity screening battery | 42868902                                 | MERCK & CO., INC. | OWN           |       |
| 870.6200                                                       | Neurotoxicity screening battery | 43868104                                 | MERCK & CO., INC. | OWN           |       |
| 870.7485                                                       | Metabolism and pharmacokinetics | 42743640                                 | MERCK & CO., INC. | OWN           |       |
| 870.7485                                                       | Metabolism and pharmacokinetics | 42743641                                 | MERCK & CO., INC. | OWN           |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 11 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name                                                  | MRID     | Submitter         | Status | Notes |
|----------------------------|-------------------------------------------------------|----------|-------------------|--------|-------|
| 870.7485                   | Metabolism and pharmacokinetics                       | 44030601 | MERCK & CO., INC. | OWN    |       |
| 870.7600                   | Dermal penetration                                    | 43850113 | MERCK & CO., INC. | OWN    |       |
| 810.1000                   | Product Performance. Overview, Definitions and Gen    | 47153901 | SYNGENTA          | OWN    |       |
| 810.1000                   | Product Performance. Overview, Definitions and Gen    | 47153902 | SYNGENTA          | OWN    |       |
| 810.1000                   | Product Performance. Overview, Definitions and Gen    | 47465501 | SYNGENTA          | OWN    |       |
| 810.1000                   | Product Performance. Overview, Definitions and Gen    | 47691001 | SYNGENTA          | OWN    |       |
| 810.1000                   | Product Performance. Overview, Definitions and Gen    | 47878901 | SYNGENTA          | OWN    |       |
| 810.3000                   | General Considerations for Efficacy of Invertebrate C | 47153901 | SYNGENTA          | OWN    |       |
| 810.3000                   | General Considerations for Efficacy of Invertebrate C | 47153902 | SYNGENTA          | OWN    |       |
| 810.3500                   | Premise Treatments                                    | 47153901 | SYNGENTA          | OWN    |       |
| 810.3500                   | Premise Treatments                                    | 47153902 | SYNGENTA          | OWN    |       |
| 810.3500                   | Premise Treatments                                    | 47153903 | SYNGENTA          | OWN    |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

| Date: 5/16/2011                                                |                                                         | Reg. No: 100-1270                        |                   | Page 12 of 24 |       |
|----------------------------------------------------------------|---------------------------------------------------------|------------------------------------------|-------------------|---------------|-------|
| Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419 |                                                         | Product: EMAMECTIN BENZOATE TECHNICAL II |                   |               |       |
| Ingredient: Emamectin Benzoate                                 |                                                         |                                          |                   |               |       |
| Guideline Reference Number                                     | Name                                                    | MRID                                     | Submitter         | Status        | Notes |
| 850.4400                                                       | Aquatic plant toxicity test using Lemna spp. Tiers I an | 43850108                                 | MERCK & CO., INC. | OWN           |       |
| 850.4400                                                       | Aquatic plant toxicity test using Lemna spp. Tiers I an | 43850109                                 | MERCK & CO., INC. | OWN           |       |
| 850.5400                                                       | Algal toxicity, Tiers 1 and 2                           | 43850108                                 | MERCK & CO., INC. | OWN           |       |
| 850.5400                                                       | Algal toxicity, Tiers 1 and 2                           | 43850109                                 | MERCK & CO., INC. | OWN           |       |
| 875.2100                                                       | Foliar dislodgeable residue dissipation                 | 43850126                                 | MERCK & CO., INC. | OWN           |       |
| 875.2100                                                       | Foliar dislodgeable residue dissipation                 | 44007903                                 | MERCK & CO., INC. | OWN           |       |
| 875.2200                                                       | Soil residue dissipation                                | 43850126                                 | MERCK & CO., INC. | OWN           |       |
| 875.2200                                                       | Soil residue dissipation                                | 44007903                                 | MERCK & CO., INC. | OWN           |       |
| 875.2400                                                       | Dermal exposure                                         | 43850126                                 | MERCK & CO., INC. | OWN           |       |
| 875.2400                                                       | Dermal exposure                                         | 43943301                                 | MERCK & CO., INC. | OWN           |       |
| 875.2600                                                       | Biological Monitoring                                   | 43943301                                 | MERCK & CO., INC. | OWN           |       |
| 850.3020                                                       | Honey bee acute contact toxicity                        | 42851530                                 | MERCK & CO., INC. | OWN           |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 13 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name                                      | MRID     | Submitter         | Status | Notes |
|----------------------------|-------------------------------------------|----------|-------------------|--------|-------|
| 850.3030                   | Honey bee toxicity of residues on foliage | 43393006 | MERCK & CO., INC. | OWN    |       |
| 161-1                      | Hydrolysis - laboratory                   | 42743642 | MERCK & CO., INC. | OWN    |       |
| 161-2                      | Photodegradation in water - laboratory    | 43404301 | MERCK & CO., INC. | OWN    |       |
| 161-2                      | Photodegradation in water - laboratory    | 43850114 | MERCK & CO., INC. | OWN    |       |
| 161-3                      | Photodegradation in soil - laboratory     | 43404302 | MERCK & CO., INC. | OWN    |       |
| 161-3                      | Photodegradation in soil - laboratory     | 44010001 | MERCK & CO., INC. | OWN    |       |
| 161-4                      | Photodegradation in Air                   | 44007906 | MERCK & CO., INC. | OWN    |       |
| 161-4                      | Photodegradation in Air                   | 44007907 | MERCK & CO., INC. | OWN    |       |
| 162-1                      | Aeroic Soil metabolism                    | 43235101 | MERCK & CO., INC. | OWN    |       |
| 162-1                      | Aeroic Soil metabolism                    | 43404303 | MERCK & CO., INC. | OWN    |       |
| 162-1                      | Aeroic Soil metabolism                    | 43850115 | MERCK & CO., INC. | OWN    |       |
| 162-1                      | Aeroic Soil metabolism                    | 44007905 | MERCK & CO., INC. | OWN    |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 14 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name                                            | MRID     | Submitter         | Status | Notes |
|----------------------------|-------------------------------------------------|----------|-------------------|--------|-------|
| 162-1                      | Aerobic Soil metabolism                         | 44010001 | MERCK & CO., INC. | OWN    |       |
| 162-2                      | Anaerobic Soil Metabolism                       | 43850116 | MERCK & CO., INC. | OWN    |       |
| 163-1                      | Leaching and adsorption/desorption – laboratory | 42743643 | MERCK & CO., INC. | OWN    |       |
| 163-1                      | Leaching and adsorption/desorption – laboratory | 43850117 | MERCK & CO., INC. | OWN    |       |
| 164-1                      | Soil dissipation – field                        | 43404304 | MERCK & CO., INC. | OWN    |       |
| 164-1                      | Soil dissipation – field                        | 43850118 | MERCK & CO., INC. | OWN    |       |
| 171-11                     | Crop field trials                               | 44715103 | SYNGENTA          | OWN    |       |
| 860.1000                   | Background                                      | 44715103 | SYNGENTA          | OWN    |       |
| 860.1000                   | Background                                      | 46587001 | SYNGENTA          | OWN    |       |
| 860.1000                   | Background                                      | 46587002 | SYNGENTA          | OWN    |       |
| 860.1000                   | Background                                      | 47723501 | SYNGENTA          | OWN    |       |
| 860.1300                   | Nature of the residue – plants, livestock       | 42851522 | MERCK & CO., INC. | OWN    |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 15 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name                                      | MRID     | Submitter         | Status | Notes |
|----------------------------|-------------------------------------------|----------|-------------------|--------|-------|
| 860.1300                   | Nature of the residue – plants, livestock | 42868904 | MERCK & CO., INC. | OWN    |       |
| 860.1300                   | Nature of the residue – plants, livestock | 43404307 | MERCK & CO., INC. | OWN    |       |
| 860.1300                   | Nature of the residue – plants, livestock | 43850121 | MERCK & CO., INC. | OWN    |       |
| 860.1300                   | Nature of the residue – plants, livestock | 43850122 | MERCK & CO., INC. | OWN    |       |
| 860.1300                   | Nature of the residue – plants, livestock | 43850123 | MERCK & CO., INC. | OWN    |       |
| 860.1300                   | Nature of the residue – plants, livestock | 43850124 | MERCK & CO., INC. | OWN    |       |
| 860.1300                   | Nature of the residue – plants, livestock | 43850125 | MERCK & CO., INC. | OWN    |       |
| 860.1300                   | Nature of the residue – plants, livestock | 44007904 | MERCK & CO., INC. | OWN    |       |
| 860.1300                   | Nature of the residue – plants, livestock | 44007906 | MERCK & CO., INC. | OWN    |       |
| 860.1300                   | Nature of the residue – plants, livestock | 44007907 | MERCK & CO., INC. | OWN    |       |
| 860.1300                   | Nature of the residue – plants, livestock | 44300102 | MERCK & CO., INC. | OWN    |       |
| 860.1300                   | Nature of the residue – plants, livestock | 44300107 | MERCK & CO., INC. | OWN    |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 16 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name                                      | MRID     | Submitter         | Status | Notes |
|----------------------------|-------------------------------------------|----------|-------------------|--------|-------|
| 860.1300                   | Nature of the residue – plants, livestock | 44313201 | MERCK & CO., INC. | OWN    |       |
| 860.1300                   | Nature of the residue – plants, livestock | 44596301 | SYNGENTA          | OWN    |       |
| 860.1300                   | Nature of the residue – plants, livestock | 44883710 | SYNGENTA          | OWN    |       |
| 860.1300                   | Nature of the residue – plants, livestock | 44883711 | SYNGENTA          | OWN    |       |
| 860.1300                   | Nature of the residue – plants, livestock | 44883712 | SYNGENTA          | OWN    |       |
| 860.1300                   | Nature of the residue – plants, livestock | 44883713 | SYNGENTA          | OWN    |       |
| 860.1300                   | Nature of the residue – plants, livestock | 44883714 | SYNGENTA          | OWN    |       |
| 860.1300                   | Nature of the residue – plants, livestock | 45209801 | SYNGENTA          | OWN    |       |
| 860.1340                   | Residue analytical method                 | 42851520 | MERCK & CO., INC. | OWN    |       |
| 860.1340                   | Residue analytical method                 | 42851521 | MERCK & CO., INC. | OWN    |       |
| 860.1340                   | Residue analytical method                 | 42868903 | MERCK & CO., INC. | OWN    |       |
| 860.1340                   | Residue analytical method                 | 43393011 | MERCK & CO., INC. | OWN    |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street  
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 17 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name                      | MRID     | Submitter         | Status | Notes |
|----------------------------|---------------------------|----------|-------------------|--------|-------|
| 860.1340                   | Residue analytical method | 43393012 | MERCK & CO., INC. | OWN    |       |
| 860.1340                   | Residue analytical method | 43415301 | MERCK & CO., INC. | OWN    |       |
| 860.1340                   | Residue analytical method | 43850121 | MERCK & CO., INC. | OWN    |       |
| 860.1340                   | Residue analytical method | 43850122 | MERCK & CO., INC. | OWN    |       |
| 860.1340                   | Residue analytical method | 44030602 | MERCK & CO., INC. | OWN    |       |
| 860.1340                   | Residue analytical method | 44300101 | MERCK & CO., INC. | OWN    |       |
| 860.1340                   | Residue analytical method | 44300103 | MERCK & CO., INC. | OWN    |       |
| 860.1340                   | Residue analytical method | 44300106 | MERCK & CO., INC. | OWN    |       |
| 860.1340                   | Residue analytical method | 44596301 | SYNGENTA          | OWN    |       |
| 860.1340                   | Residue analytical method | 44795001 | SYNGENTA          | OWN    |       |
| 860.1340                   | Residue analytical method | 44883707 | SYNGENTA          | OWN    |       |
| 860.1340                   | Residue analytical method | 44883708 | SYNGENTA          | OWN    |       |

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 18 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name                      | MRID     | Submitter | Status | Notes |
|----------------------------|---------------------------|----------|-----------|--------|-------|
| 860.1340                   | Residue analytical method | 44883709 | SYNGENTA  | OWN    |       |
| 860.1340                   | Residue analytical method | 44883715 | SYNGENTA  | OWN    |       |
| 860.1340                   | Residue analytical method | 44883716 | SYNGENTA  | OWN    |       |
| 860.1340                   | Residue analytical method | 45209801 | SYNGENTA  | OWN    |       |
| 860.1340                   | Residue analytical method | 45209802 | SYNGENTA  | OWN    |       |
| 860.1340                   | Residue analytical method | 45209803 | SYNGENTA  | OWN    |       |
| 860.1340                   | Residue analytical method | 45899801 | SYNGENTA  | OWN    |       |
| 860.1340                   | Residue analytical method | 48170001 | SYNGENTA  | OWN    |       |
| 860.1340                   | Residue analytical method | 48170002 | SYNGENTA  | OWN    |       |
| 860.1380                   | Storage stability data    | 46734701 | SYNGENTA  | OWN    |       |
| 860.1380                   | Storage stability data    | 47296001 | SYNGENTA  | OWN    |       |
| 860.1380                   | Storage stability data    | 48193601 | SYNGENTA  | OWN    |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 19 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name                                      | MRID     | Submitter         | Status | Notes |
|----------------------------|-------------------------------------------|----------|-------------------|--------|-------|
| 860.1500                   | Crop field trials                         | 44715103 | SYNGENTA          | OWN    |       |
| 860.1500                   | Crop field trials                         | 45209802 | SYNGENTA          | OWN    |       |
| 860.1500                   | Crop field trials                         | 45209803 | SYNGENTA          | OWN    |       |
| 860.1500                   | Crop field trials                         | 46587001 | SYNGENTA          | OWN    |       |
| 860.1500                   | Crop field trials                         | 46587002 | SYNGENTA          | OWN    |       |
| 860.1500                   | Crop field trials                         | 46783701 | SYNGENTA          | OWN    |       |
| 860.1500                   | Crop field trials                         | 47002101 | SYNGENTA          | OWN    |       |
| 860.1500                   | Crop field trials                         | 47243301 | SYNGENTA          | OWN    |       |
| 860.1500                   | Crop field trials                         | 47723501 | SYNGENTA          | OWN    |       |
| 860.1520                   | Processed food/feed                       | 46587002 | SYNGENTA          | OWN    |       |
| 860.1520                   | Processed food/feed                       | 46783701 | SYNGENTA          | OWN    |       |
| 860.1850                   | Confined accumulation in rotational crops | 43850119 | MERCK & CO., INC. | OWN    |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 20 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name                                                     | MRID     | Submitter         | Status | Notes |
|----------------------------|----------------------------------------------------------|----------|-------------------|--------|-------|
| 850.1010                   | Aquatic invertigrate acute toxicity test, freshwater dap | 42743603 | MERCK & CO., INC. | OWN    |       |
| 850.1010                   | Aquatic invertigrate acute toxicity test, freshwater dap | 44007901 | MERCK & CO., INC. | OWN    |       |
| 850.1025                   | Oyster acute toxicity test (shell deposition)            | 43393001 | MERCK & CO., INC. | OWN    |       |
| 850.1025                   | Oyster acute toxicity test (shell deposition)            | 43393002 | MERCK & CO., INC. | OWN    |       |
| 850.1025                   | Oyster acute toxicity test (shell deposition)            | 43393003 | MERCK & CO., INC. | OWN    |       |
| 850.1025                   | Oyster acute toxicity test (shell deposition)            | 44007912 | MERCK & CO., INC. | OWN    |       |
| 850.1025                   | Oyster acute toxicity test (shell deposition)            | 44007913 | MERCK & CO., INC. | OWN    |       |
| 850.1025                   | Oyster acute toxicity test (shell deposition)            | 44007914 | MERCK & CO., INC. | OWN    |       |
| 850.1035                   | Mysid acute toxicity test                                | 43393001 | MERCK & CO., INC. | OWN    |       |
| 850.1035                   | Mysid acute toxicity test                                | 43393002 | MERCK & CO., INC. | OWN    |       |
| 850.1035                   | Mysid acute toxicity test                                | 43393003 | MERCK & CO., INC. | OWN    |       |
| 850.1035                   | Mysid acute toxicity test                                | 44007912 | MERCK & CO., INC. | OWN    |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 21 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name                                        | MRID     | Submitter         | Status | Notes |
|----------------------------|---------------------------------------------|----------|-------------------|--------|-------|
| 850.1035                   | Mysid acute toxicity test                   | 44007913 | MERCK & CO., INC. | OWN    |       |
| 850.1035                   | Mysid acute toxicity test                   | 44007914 | MERCK & CO., INC. | OWN    |       |
| 850.1045                   | Penaeid acute toxicity test                 | 43393001 | MERCK & CO., INC. | OWN    |       |
| 850.1045                   | Penaeid acute toxicity test                 | 43393002 | MERCK & CO., INC. | OWN    |       |
| 850.1045                   | Penaeid acute toxicity test                 | 43393003 | MERCK & CO., INC. | OWN    |       |
| 850.1045                   | Penaeid acute toxicity test                 | 44007912 | MERCK & CO., INC. | OWN    |       |
| 850.1045                   | Penaeid acute toxicity test                 | 44007913 | MERCK & CO., INC. | OWN    |       |
| 850.1045                   | Penaeid acute toxicity test                 | 44007914 | MERCK & CO., INC. | OWN    |       |
| 850.1055                   | Bivalve acute toxicity test (embryo larval) | 43393001 | MERCK & CO., INC. | OWN    |       |
| 850.1055                   | Bivalve acute toxicity test (embryo larval) | 43393002 | MERCK & CO., INC. | OWN    |       |
| 850.1055                   | Bivalve acute toxicity test (embryo larval) | 43393003 | MERCK & CO., INC. | OWN    |       |
| 850.1055                   | Bivalve acute toxicity test (embryo larval) | 44007912 | MERCK & CO., INC. | OWN    |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 22 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name                                            | MRID     | Submitter         | Status | Notes |
|----------------------------|-------------------------------------------------|----------|-------------------|--------|-------|
| 850.1055                   | Bivalve acute toxicity test (embryo larval)     | 44007913 | MERCK & CO., INC. | OWN    |       |
| 850.1055                   | Bivalve acute toxicity test (embryo larval)     | 44007914 | MERCK & CO., INC. | OWN    |       |
| 850.1075                   | Fish acute toxicity test, freshwater and marine | 42743602 | MERCK & CO., INC. | OWN    |       |
| 850.1075                   | Fish acute toxicity test, freshwater and marine | 42851529 | MERCK & CO., INC. | OWN    |       |
| 850.1075                   | Fish acute toxicity test, freshwater and marine | 43393001 | MERCK & CO., INC. | OWN    |       |
| 850.1075                   | Fish acute toxicity test, freshwater and marine | 43393002 | MERCK & CO., INC. | OWN    |       |
| 850.1075                   | Fish acute toxicity test, freshwater and marine | 43393003 | MERCK & CO., INC. | OWN    |       |
| 850.1075                   | Fish acute toxicity test, freshwater and marine | 43850106 | MERCK & CO., INC. | OWN    |       |
| 850.1075                   | Fish acute toxicity test, freshwater and marine | 44007912 | MERCK & CO., INC. | OWN    |       |
| 850.1075                   | Fish acute toxicity test, freshwater and marine | 44007913 | MERCK & CO., INC. | OWN    |       |
| 850.1075                   | Fish acute toxicity test, freshwater and marine | 44007914 | MERCK & CO., INC. | OWN    |       |
| 850.1300                   | Daphnid chronic toxicity test                   | 43393004 | MERCK & CO., INC. | OWN    |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 23 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name                                | MRID     | Submitter         | Status | Notes |
|----------------------------|-------------------------------------|----------|-------------------|--------|-------|
| 850.1300                   | Daphnid chronic toxicity test       | 43850107 | MERCK & CO., INC. | OWN    |       |
| 850.1300                   | Daphnid chronic toxicity test       | 44305601 | MERCK & CO., INC. | OWN    |       |
| 850.1300                   | Daphnid chronic toxicity test       | 45833001 | SYNGENTA          | OWN    |       |
| 850.1350                   | Mysid chronic toxicity test         | 43393004 | MERCK & CO., INC. | OWN    |       |
| 850.1350                   | Mysid chronic toxicity test         | 43850107 | MERCK & CO., INC. | OWN    |       |
| 850.1350                   | Mysid chronic toxicity test         | 44305601 | MERCK & CO., INC. | OWN    |       |
| 850.1350                   | Mysid chronic toxicity test         | 45833001 | SYNGENTA          | OWN    |       |
| 850.1400                   | Fish early-life stage toxicity test | 43393004 | MERCK & CO., INC. | OWN    |       |
| 850.1400                   | Fish early-life stage toxicity test | 43850107 | MERCK & CO., INC. | OWN    |       |
| 850.1400                   | Fish early-life stage toxicity test | 44305601 | MERCK & CO., INC. | OWN    |       |
| 850.1400                   | Fish early-life stage toxicity test | 45833001 | SYNGENTA          | OWN    |       |
| 850.1710                   | Oyster BCF                          | 43393005 | MERCK & CO., INC. | OWN    |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 24 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name                           | MRID     | Submitter         | Status | Notes |
|----------------------------|--------------------------------|----------|-------------------|--------|-------|
| 850.1730                   | Accumulation in fish -- waiver | 43393005 | MERCK & CO., INC. | OWN    |       |
| 850.1850                   | Aquatic organism accumulation  | 43393005 | MERCK & CO., INC. | OWN    |       |
| 850.2100                   | Avian acute oral toxicity test | 42743601 | MERCK & CO., INC. | OWN    |       |
| 850.2100                   | Avian acute oral toxicity test | 42868905 | MERCK & CO., INC. | OWN    |       |
| 850.2200                   | Avian dietary toxicity test    | 42851527 | MERCK & CO., INC. | OWN    |       |
| 850.2200                   | Avian dietary toxicity test    | 42851528 | MERCK & CO., INC. | OWN    |       |
| 850.2300                   | Avian reproduction test        | 43850104 | MERCK & CO., INC. | OWN    |       |
| 850.2300                   | Avian reproduction test        | 43850105 | MERCK & CO., INC. | OWN    |       |
| 850.2300                   | Avian reproduction test        | 44007910 | MERCK & CO., INC. | OWN    |       |
| 850.2300                   | Avian reproduction test        | 44007911 | MERCK & CO., INC. | OWN    |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street  
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 1 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name | MRID | Submitter         | Status | Notes |
|----------------------------|------|------|-------------------|--------|-------|
|                            |      |      | AGRICULTURAL HAN  | PER    |       |
|                            |      |      | AGRICULTURAL REE  | PER    |       |
|                            |      |      | FIFRA ENDANGERED  | PER    |       |
|                            |      |      | OUTDOOR RESIDENT  | PER    |       |
|                            |      |      | RESIDENTIAL EXPOS | PER    |       |
|                            |      |      | SPRAY DRIFT TF    | PER    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011

E-SUBMISSION

387





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 2 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Enamectin Benzoate

| Guideline Reference Number | Name | MRID | Submitter | Status | Notes |
|----------------------------|------|------|-----------|--------|-------|
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 3 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name | MRID | Submitter | Status | Notes |
|----------------------------|------|------|-----------|--------|-------|
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 4 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name | MRID | Submitter | Status | Notes |
|----------------------------|------|------|-----------|--------|-------|
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street  
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 5 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name | MRID | Submitter | Status | Notes |
|----------------------------|------|------|-----------|--------|-------|
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 6 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name | MRID | Submitter         | Status | Notes |
|----------------------------|------|------|-------------------|--------|-------|
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street  
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 7 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Eamectin Benzoate

| Guideline Reference Number | Name | MRID | Submitter         | Status | Notes |
|----------------------------|------|------|-------------------|--------|-------|
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 8 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name | MRID | Submitter         | Status | Notes |
|----------------------------|------|------|-------------------|--------|-------|
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 9 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name | MRID | Submitter         | Status | Notes |
|----------------------------|------|------|-------------------|--------|-------|
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 10 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name | MRID | Submitter         | Status | Notes |
|----------------------------|------|------|-------------------|--------|-------|
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street  
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 11 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name | MRID | Submitter         | Status | Notes |
|----------------------------|------|------|-------------------|--------|-------|
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 12 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name | MRID | Submitter         | Status | Notes |
|----------------------------|------|------|-------------------|--------|-------|
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street  
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 13 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name | MRID | Submitter         | Status | Notes |
|----------------------------|------|------|-------------------|--------|-------|
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 14 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name | MRID | Submitter         | Status | Notes |
|----------------------------|------|------|-------------------|--------|-------|
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street  
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 15 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Enamectin Benzoate

| Guideline Reference Number | Name | MRID | Submitter         | Status | Notes |
|----------------------------|------|------|-------------------|--------|-------|
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 16 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name | MRID | Submitter         | Status | Notes |
|----------------------------|------|------|-------------------|--------|-------|
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street  
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 17 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name | MRID | Submitter         | Status | Notes |
|----------------------------|------|------|-------------------|--------|-------|
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 18 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name | MRID | Submitter | Status | Notes |
|----------------------------|------|------|-----------|--------|-------|
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street  
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 19 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name | MRID | Submitter         | Status | Notes |
|----------------------------|------|------|-------------------|--------|-------|
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street  
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 20 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name | MRID | Submitter         | Status | Notes |
|----------------------------|------|------|-------------------|--------|-------|
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 21 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name | MRID | Submitter         | Status | Notes |
|----------------------------|------|------|-------------------|--------|-------|
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 22 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name | MRID | Submitter         | Status | Notes |
|----------------------------|------|------|-------------------|--------|-------|
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 23 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name | MRID | Submitter         | Status | Notes |
|----------------------------|------|------|-------------------|--------|-------|
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street  
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: 5/16/2011

Reg. No: 100-1270

Page 24 of 24

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: EMAMECTIN BENZOATE TECHNICAL II

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name | MRID | Submitter         | Status | Notes |
|----------------------------|------|------|-------------------|--------|-------|
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street  
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: 5/16/2011

Reg. No: 100-XXXX

Page 1 of 6

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: Enfold

Ingredient: Eamectin Benzoate

| Guideline Reference Number | Name                                                 | MRID           | Submitter         | Status | Notes |
|----------------------------|------------------------------------------------------|----------------|-------------------|--------|-------|
| Cite-All                   | Cite-All                                             | Cite-All (AHE) | AGRICULTURAL HAN  | PER    |       |
| Cite-All                   | Cite-All                                             | Cite-All (ART) | AGRICULTURAL REE  | PER    |       |
| Cite-All                   | Cite-All                                             | Cite-All (FES) | FIFRA ENDANGERED  | PER    |       |
| Cite-All                   | Cite-All                                             | Cite-All (ORE) | OUTDOOR RESIDENT  | PER    |       |
| Cite-All                   | Cite-All                                             | Cite-All (REJ) | RESIDENTIAL EXPOS | PER    |       |
| Cite-All                   | Cite-All                                             | Cite-All (SDT) | SPRAY DRIFT TF    | PER    |       |
| 830.0000                   | Product identity and composition                     | 42743644       | MERCK & CO., INC. | OWN    |       |
| 830.0000                   | Product identity and composition                     | 43824001       | MERCK & CO., INC. | OWN    |       |
| 830.0000                   | Product identity and composition                     | 43824002       | MERCK & CO., INC. | OWN    |       |
| 830.0000                   | Product identity and composition                     | 44883705       | SYNGENTA          | OWN    |       |
| 830.1600                   | Description of materials used to produce the product | 44883701       | SYNGENTA          | OWN    |       |
| 830.1620                   | Description of production process                    | 44883701       | SYNGENTA          | OWN    |       |

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011

E-SUBMISSION

411





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

| Date: 5/16/2011                                                |                                                           | Reg. No: 100-XXXX |                   | Page 2 of 6 |       |
|----------------------------------------------------------------|-----------------------------------------------------------|-------------------|-------------------|-------------|-------|
| Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419 |                                                           | Product: Enfold   |                   |             |       |
| Ingredient: Enamectin Benzoate                                 |                                                           |                   |                   |             |       |
| Guideline Reference Number                                     | Name                                                      | MRID              | Submitter         | Status      | Notes |
| 830.1650                                                       | Description of Formulation process                        | 44883701          | SYNGENTA          | OWN         |       |
| 830.1750                                                       | Certified limits                                          | 43824001          | MERCK & CO., INC. | OWN         |       |
| 830.1800                                                       | Enforcement analytical method                             | 43824001          | MERCK & CO., INC. | OWN         |       |
| 830.1800                                                       | Enforcement analytical method                             | 44007908          | MERCK & CO., INC. | OWN         |       |
| 830.1800                                                       | Enforcement analytical method                             | 44007909          | MERCK & CO., INC. | OWN         |       |
| 830.6313                                                       | Stability to normal and elevated temperatures, metals,    | 43850103          | MERCK & CO., INC. | OWN         |       |
| 830.7000                                                       | pH                                                        | 44883702          | SYNGENTA          | OWN         |       |
| 830.7550                                                       | Partition coefficient (n-octanol/water), shake flask met  | 44883703          | SYNGENTA          | OWN         |       |
| 830.7560                                                       | Partition coefficient (n-octanol/water), generator colu   | 44883703          | SYNGENTA          | OWN         |       |
| 830.7570                                                       | Partition coefficient (n-octanol/water), estimation by li | 44883703          | SYNGENTA          | OWN         |       |
| 830.7840                                                       | Water solubility: column elution method, shake flask      | 44883704          | SYNGENTA          | OWN         |       |
| 830.7860                                                       | Water solubility: generator column method                 | 44883704          | SYNGENTA          | OWN         |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street  
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

| Date: 5/16/2011                                                |                                            | Reg. No: 100-XXXX |                   | Page 3 of 6 |       |
|----------------------------------------------------------------|--------------------------------------------|-------------------|-------------------|-------------|-------|
| Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419 |                                            | Product: Enfold   |                   |             |       |
| Ingredient: Enamectin Benzoate                                 |                                            |                   |                   |             |       |
| Guideline Reference Number                                     | Name                                       | MRID              | Submitter         | Status      | Notes |
| 870.1100                                                       | Acute oral toxicity                        | 43824003          | MERCK & CO., INC. | OWN         |       |
| 870.1200                                                       | Acute dermal toxicity                      | 43824004          | MERCK & CO., INC. | OWN         |       |
| 870.2400                                                       | Acute eye irritation                       | 42743615          | MERCK & CO., INC. | OWN         |       |
| 870.2400                                                       | Acute eye irritation                       | 43824005          | MERCK & CO., INC. | OWN         |       |
| 870.2500                                                       | Acute dermal irritation                    | 42743616          | MERCK & CO., INC. | OWN         |       |
| 860.1000                                                       | Background                                 | 46587001          | SYNGENTA          | OWN         |       |
| 860.1000                                                       | Background                                 | 46587002          | SYNGENTA          | OWN         |       |
| 860.1000                                                       | Background                                 | 47723501          | SYNGENTA          | OWN         |       |
| 860.1300                                                       | Nature of the residue -- plants, livestock | 44596301          | SYNGENTA          | OWN         |       |
| 860.1300                                                       | Nature of the residue -- plants, livestock | 44883710          | SYNGENTA          | OWN         |       |
| 860.1300                                                       | Nature of the residue -- plants, livestock | 44883711          | SYNGENTA          | OWN         |       |
| 860.1300                                                       | Nature of the residue -- plants, livestock | 44883712          | SYNGENTA          | OWN         |       |

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street  
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: 5/16/2011

Reg. No: 100-XXXX

Page 4 of 6

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: Enfold

Ingredient: Enamectin Benzoate

| Guideline Reference Number | Name                                      | MRID     | Submitter | Status | Notes |
|----------------------------|-------------------------------------------|----------|-----------|--------|-------|
| 860.1300                   | Nature of the residue – plants, livestock | 44883713 | SYNGENTA  | OWN    |       |
| 860.1300                   | Nature of the residue – plants, livestock | 44883714 | SYNGENTA  | OWN    |       |
| 860.1300                   | Nature of the residue – plants, livestock | 45209801 | SYNGENTA  | OWN    |       |
| 860.1340                   | Residue analytical method                 | 44596301 | SYNGENTA  | OWN    |       |
| 860.1340                   | Residue analytical method                 | 44795001 | SYNGENTA  | OWN    |       |
| 860.1340                   | Residue analytical method                 | 44883707 | SYNGENTA  | OWN    |       |
| 860.1340                   | Residue analytical method                 | 44883708 | SYNGENTA  | OWN    |       |
| 860.1340                   | Residue analytical method                 | 44883709 | SYNGENTA  | OWN    |       |
| 860.1340                   | Residue analytical method                 | 44883715 | SYNGENTA  | OWN    |       |
| 860.1340                   | Residue analytical method                 | 44883716 | SYNGENTA  | OWN    |       |
| 860.1340                   | Residue analytical method                 | 45209801 | SYNGENTA  | OWN    |       |
| 860.1340                   | Residue analytical method                 | 45209802 | SYNGENTA  | OWN    |       |

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street  
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: 5/16/2011

Reg. No: 100-XXXX

Page 5 of 6

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: Enfold

Ingredient: Emaxectin Benzoate

| Guideline Reference Number | Name                      | MRID     | Submitter | Status | Notes |
|----------------------------|---------------------------|----------|-----------|--------|-------|
| 860.1340                   | Residue analytical method | 45209803 | SYNGENTA  | OWN    |       |
| 860.1340                   | Residue analytical method | 45899801 | SYNGENTA  | OWN    |       |
| 860.1380                   | Storage stability data    | 46734701 | SYNGENTA  | OWN    |       |
| 860.1380                   | Storage stability data    | 48193601 | SYNGENTA  | OWN    |       |
| 860.1500                   | Crop field trials         | 45209802 | SYNGENTA  | OWN    |       |
| 860.1500                   | Crop field trials         | 45209803 | SYNGENTA  | OWN    |       |
| 860.1500                   | Crop field trials         | 46587001 | SYNGENTA  | OWN    |       |
| 860.1500                   | Crop field trials         | 46587002 | SYNGENTA  | OWN    |       |
| 860.1500                   | Crop field trials         | 46783701 | SYNGENTA  | OWN    |       |
| 860.1500                   | Crop field trials         | 47243301 | SYNGENTA  | OWN    |       |
| 860.1500                   | Crop field trials         | 47723501 | SYNGENTA  | OWN    |       |
| 860.1520                   | Processed food/feed       | 46587002 | SYNGENTA  | OWN    |       |

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/16/2011

Reg. No: 100-XXXX

Page 6 of 6

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: Enfold

Ingredient: Enamectin Benzoate

| Guideline Reference Number | Name                                | MRID     | Submitter | Status | Notes |
|----------------------------|-------------------------------------|----------|-----------|--------|-------|
| 860.1520                   | Processed food/feed                 | 46783701 | SYNGENTA  | OWN    |       |
| 850.1300                   | Daphnid chronic toxicity test       | 45833001 | SYNGENTA  | OWN    |       |
| 850.1350                   | Mysid chronic toxicity test         | 45833001 | SYNGENTA  | OWN    |       |
| 850.1400                   | Fish early-life stage toxicity test | 45833001 | SYNGENTA  | OWN    |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street  
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: 5/16/2011

Reg. No: 100-XXXX

Page 1 of 6

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: Enfold

Ingredient: Enamectin Benzoate

| Guideline Reference Number | Name | MRID | Submitter         | Status | Notes |
|----------------------------|------|------|-------------------|--------|-------|
|                            |      |      | AGRICULTURAL HAN  | PER    |       |
|                            |      |      | AGRICULTURAL REE  | PER    |       |
|                            |      |      | FIFRA ENDANGERED  | PER    |       |
|                            |      |      | OUTDOOR RESIDENT  | PER    |       |
|                            |      |      | RESIDENTIAL EXPOS | PER    |       |
|                            |      |      | SPRAY DRIFT TF    | PER    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011

F-SUBMISSION

417





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street  
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: 5/16/2011

Reg. No: 100-XXXX

Page 2 of 6

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: Enfold

Ingredient: Enamectin Benzoate

| Guideline Reference Number | Name | MRID | Submitter         | Status | Notes |
|----------------------------|------|------|-------------------|--------|-------|
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street  
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: 5/16/2011

Reg. No: 100-XXXX

Page 3 of 6

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: Enfold

Ingredient: Enamectin Benzoate

| Guideline Reference Number | Name | MRID | Submitter         | Status | Notes |
|----------------------------|------|------|-------------------|--------|-------|
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | MERCK & CO., INC. | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |
|                            |      |      | SYNGENTA          | OWN    |       |

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street  
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: 5/16/2011

Reg. No: 100-XXXX

Page 4 of 6

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: Enfold

Ingredient: Enamectin Benzoate

| Guideline Reference Number | Name | MRID | Submitter | Status | Notes |
|----------------------------|------|------|-----------|--------|-------|
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street  
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: 5/16/2011

Reg. No: 100-XXXX

Page 5 of 6

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: Enfold

Ingredient: Enamectin Benzoate

| Guideline Reference Number | Name | MRID | Submitter | Status | Notes |
|----------------------------|------|------|-----------|--------|-------|
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 5/16/2011

Reg. No: 100-XXXX

Page 6 of 6

Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419

Product: Enfold

Ingredient: Emamectin Benzoate

| Guideline Reference Number | Name | MRID | Submitter | Status | Notes |
|----------------------------|------|------|-----------|--------|-------|
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |
|                            |      |      | SYNGENTA  | OWN    |       |

*Thomas J. Parshley*

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 5/16/2011

(Booklet)

**RESTRICTED USE PESTICIDE**

**TOXIC TO FISH, MAMMALS, AND AQUATIC ORGANISMS**

FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR  
DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S  
CERTIFICATION.

Enfold™  
Insecticide

**GROUP 6 INSECTICIDE**

For control of listed lepidopterous larvae (worms/caterpillars) and suppression of  
leafminers and spider mites on outdoor-grown plants in commercial nursery production

|                                               |        |
|-----------------------------------------------|--------|
| Active Ingredient:                            |        |
| Emamectin benzoate (CAS No. 155569-91-8)..... | 5.0%   |
| Other Ingredients:                            | 95.0%  |
| Total:                                        | 100.0% |

Enfold Insecticide is a soluble granule containing 5% emamectin benzoate.

**KEEP OUT OF REACH OF CHILDREN.**

**CAUTION**

See additional precautionary statements and directions for use in booklet.

EPA Reg. No. 100-XXXX

EPA Est. XXXXX

Product of XXXXX  
Formulated in XXXXX

SCP

Net Weight

**E-SUBMISSION**



| <b>FIRST AID</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                            |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>If swallowed</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <ul style="list-style-type: none"> <li>• Call poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul> |
| <b>If in eyes</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>                                                    |
| <b>If on skin or clothing</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>                                                                                                                      |
| <b>If inhaled</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>                                                |
| <p align="center"><b>NOTE TO PHYSICIAN</b></p> <p>Early signs of intoxication include dilation of pupils, muscular incoordination, and muscular tremors. Vomiting within one-half hour of exposure can minimize toxicity following accidental ingestion of the product; rapidly after exposure (&lt; 15 minutes), administer repeatedly medical charcoal in a large quantity of water or ipecac.</p> <p>If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements.</p> <p>In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since emamectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic emamectin benzoate exposure.</p> <p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p> |                                                                                                                                                                                                                                                                                                                                                            |

MISSION



**HOT LINE NUMBER**

For 24-Hour Medical Emergency Assistance (Human or Animal)  
Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident)

Call

**1-800-888-8372**

---

**PRECAUTIONARY STATEMENTS**

---

**Hazards to Humans and Domestic Animals**

**CAUTION**

Harmful if swallowed, inhaled, or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Avoid breathing dust or spray mist. Prolonged or frequently repeated exposure may cause allergic skin reactions in some individuals.

**Personal Protective Equipment (PPE)**

• **Ground Application (except airblast sprayers):**

**Applicators, mixers, loaders, and other handlers must wear:**

- Long-sleeved shirt and long pants
- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber
- Shoes plus socks

• **Airblast Application:**

**Mixers, loaders, and other handlers must wear:**

- Long-sleeved shirt and long pants
- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber
- Shoes plus socks

**Applicators using OPEN CAB airblast sprayers must wear:**

- Coveralls over long-sleeved shirt and long pants
- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber
- Shoes plus socks

### **Applicators using ENCLOSED CAB airblast sprayers**

#### **While inside the cab must wear:**

- Long-sleeved shirt and long pants
- Shoes plus socks

#### **When entering or leaving the cab must also wear:**

- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber.

**NOTE:** Once inside the cab, applicator must remove gloves and store them in a chemical-resistant container such as a plastic bag.

- **Aerial application:**

#### **Mixers, loaders, and other handlers must wear:**

- Coveralls over long-sleeved shirt and long pants
- Shoes plus socks
- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber
- Dust/Mist-filtering respirator or a NIOSH-approved respirator with any N, R, P, or HE filter

### **Applicators (Enclosed Cockpit)**

#### **While inside the cockpit must wear:**

- Long-sleeved shirt and long pants
- Shoes plus socks

#### **When entering or leaving the cockpit must also wear:**

- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber.

**NOTE:** Once inside the cockpit, applicator must remove gloves and store them in a chemical-resistant container such as a plastic bag.

#### **Flaggers must wear:**

- Long-sleeved shirt and long pants
- Shoes plus socks
- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber or butyl rubber.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.



## **Engineering Controls**

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170-240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

### **User Safety Recommendations**

#### **Users should:**

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothes immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

## **Environmental Hazards**

This pesticide is toxic to fish, birds, mammals, and aquatic invertebrates. Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash water or rinsate.

This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow drift to blooming crops or weeds if bees are visiting the treatment area.

### **Physical or Chemical Hazards**

Do not use or store near heat or open flame.



---

**CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY**

---

**NOTICE:** Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, LLC or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions, or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and (2) Buyer and User assume the risk of any such use. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.**

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.



## **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Enfold Insecticide must be used only in accordance with directions on this label or in separately published Syngenta supplemental labeling for this product.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

### **AGRICULTURAL USE REQUIREMENTS**

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Chemical-resistant gloves made of any waterproof material such as polyvinyl chloride, nitrile rubber, or butyl rubber
- Shoes plus socks
- Protective eyewear

**FAILURE TO FOLLOW DIRECTIONS AND PRECAUTIONS ON THIS LABEL MAY RESULT IN POOR INSECT CONTROL.**

---

### **GENERAL INFORMATION**

---

Enfold Insecticide is a selective insecticide for use on herbaceous and woody ornamental plants grown outdoors (in containers or in the ground) in commercial nursery production. Woody ornamentals include (but are not limited to) shrubs, non-bearing fruit and nut trees, Christmas trees, forest seedlings, and shade trees.

Enfold Insecticide controls the larval stages (worms/caterpillars) of listed lepidopteran species and suppresses Liriomyza leafminer, Tetranychid mites and pear psylla. Enfold Insecticide has contact activity, but is most efficacious when ingested by the pest. Shortly after exposure to Enfold Insecticide, affected larvae are paralyzed, stop feeding, and subsequently die after 2-4 days.

- Apply Enfold Insecticide to plant foliage when larvae first appear (immediately after egg hatch), but before populations reach damaging levels. Target Enfold Insecticide applications at small (1/4 inch in length) larvae.
- Treatments must be made before larvae penetrate plant parts or before larvae begin webbing and sheltering.
- Thorough spray coverage is essential for optimum performance. Apply Enfold Insecticide in sufficient water to ensure good coverage of all plant surfaces. The use of greater water volumes will generally result in better coverage, especially under adverse conditions (e.g., hot, dry) or when the plant canopy is dense.

### **Resistance Management**

Enfold Insecticide is a Group 6 insecticide (contains the active ingredient emamectin benzoate).

Because of the inherent risks of resistance development to any product, it is strongly advised that Enfold Insecticide be used in a sound resistance management program. Treatment may not be effective against labeled pests if tolerant strains of insects or mites develop. When applying Enfold Insecticide to plants that are hosts of labeled pests and these labeled pests have multiple generations per crop per year, use resistance management practices.

**Resistance management practices** may include, but are not limited to:

- Rotating Enfold Insecticide with other products with different modes of action
- Avoiding treatment of successive pest generations with Enfold Insecticide
- Using labeled rates at the specified spray intervals
- Using non-chemical alternatives such as beneficial arthropods
- Rotating susceptible to non-susceptible plants



- Using various cultural practices

For additional information regarding the implementation of these or other resistance management practices, consult your local agricultural advisor or company representative.

---

## APPLICATION PROCEDURES

---

### Application Prohibitions:

- **Chemigation:** Do not apply this product through any type of irrigation system.
- **State Restriction:** Do not apply Enfold Insecticide with aircraft in New York State.

### Spray Equipment

Apply by ground, airblast sprayer or aircraft. Spray equipment configuration should be arranged to provide accurate, uniform, and thorough coverage of the target crop and minimize potential for spray drift. Use spray nozzles that provide medium to fine-sized droplets. To ensure accuracy, calibrate sprayer before each use. For spray equipment and calibration information, consult sprayer manufacturers and/or state recommendations. All ground and aerial application equipment must be properly maintained and calibrated using appropriate carriers.

### Spray Volume

- Applications using sufficient water volume for thorough and uniform coverage of the target crop provide the most effective pest control.
- Avoid application when uniform coverage is not possible or if excessive spray drift or inversion is possible.

---

## SPRAY DRIFT

---

**NOTE:** When states have more stringent regulations, they must be observed.

### Spray Drift Precautions – Aircraft and Ground Application Equipment

Apply Enfold Insecticide only when wind velocity favors on-target product deposition (approximately 3 to 10 mph).

- **Do not** apply with ground application equipment within 25 ft. of or with aircraft within 150 ft. of lakes, reservoirs, rivers, permanent streams, marshes, pot holes, natural ponds, estuaries, or commercial fish farm ponds.

- **Do not** cultivate within 25 ft. of the aquatic area to allow growth of a vegetative filter strip.
- **Do not** allow this product to drift onto non-target areas. Drift may result in illegal residues or injury to non-target species. Risk of exposure to sensitive areas can be reduced by applying this product when the wind direction is away from the sensitive area.
- **Do not** apply when the weather conditions may cause drift:
  - Avoid application when the temperature is high and/or the humidity is low. These conditions increase the evaporation of spray droplets and the likelihood of drift to aquatic areas.
  - **Do not** apply when wind speed or wind gusts are greater than 10 mph.
  - **Do not** apply when wind speed is below 2 mph because wind direction will vary and there is a high potential for inversion.

### **Spray Drift Precautions (Aerial Application)**

#### **Responsibility**

Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment- and weather-related factors determines the potential for spray drift. The applicator is responsible for considering all of these factors when making application decisions.

#### **Drift Management Requirements**

The following drift management requirements must be followed to avoid off-target movement from aerial applications to non-target plants.

- **Outermost Nozzle Distance**  
The distance of the outermost nozzles on the boom must not exceed  $\frac{3}{4}$  the length of the wingspan or rotor.
- **Nozzle Direction**  
Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees.
- **Maximum Wind Speed**  
Do not apply when wind speed is greater than 10 mph.
- **Droplet Size**  
The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide



sufficient coverage and control. Applying larger droplets reduces drift potential but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions. (See **Wind, Temperature and Humidity**, and **Temperature Inversions** sections.)

- **Controlling Droplet Size**

- Volume**

- Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets.

- Pressure**

- Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types, lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure.

- Number of Nozzles**

- Use the minimum number of nozzles that provide uniform coverage.

- Nozzle Orientation**

- Orienting nozzles so that the spray is released parallel to the air stream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential.

- Nozzle Type**

- Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid-stream nozzles oriented straight back produce the largest droplets and the lowest drift.

- **Boom Length**

- For some use patterns, reducing the effective boom length to less than  $\frac{3}{4}$  of the wingspan or rotor length may further reduce drift without reducing swath width.

- **Application Height**

- Applications should not be made at a height greater than 10 ft. above the top of the target plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind.

- **Swath Adjustment**

- When applications are made with a cross wind, the swath will be displaced downwind. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind.

- **Wind**

Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application must be avoided below 2 mph due to variable wind direction and high inversion potential. **NOTE:** Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift.

- **Temperature and Humidity**

To compensate for evaporation when applying Enfold Insecticide in low relative humidity, set up equipment to produce larger droplets. Evaporation of droplets is most severe when conditions are both hot and dry.

- **Temperature Inversions**

Enfold Insecticide must not be applied during a temperature inversion because the potential for drift is high. Temperature inversions restrict vertical air mixing, and this causes small, suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds that are common during inversions. Temperature inversions are characterized by temperatures that increase with altitude and are common on nights with limited cloud cover and light to no wind. Inversions begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, the movement of smoke from a ground source or an aircraft smoke generator can also identify inversions. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates, indicates good vertical air mixing.

---

## **MIXING PROCEDURES**

---

1. Thoroughly clean spray equipment before using this product.
2. Prepare no more spray mixture than is needed for the immediate application.
3. Keep product container tightly closed when not in use.
4. Agitate the spray solution before and during application.
5. Do not let the spray mixture stand overnight in the spray tank.
6. Flush the spray equipment thoroughly following each use and apply rinsate to a previously treated area.

### **Mixing Instructions: Enfold Insecticide Alone**

1. Add 1/3 of the required amount of water to the spray or mixing tank.
2. With the agitator running, add Enfold Insecticide into the spray tank.
3. Continue agitation while adding the remainder of the water.



4. Begin application of the solution after Enfold Insecticide has completely dispersed into the mix water.
5. Maintain agitation until all of the mixture has been applied.

**Note:** Do not use liquid fertilizer as a carrier for Enfold Insecticide.

## **Enfold Insecticide - Tank Mixtures**

### **Compatibility**

Enfold Insecticide is compatible with most insecticide, fungicide, and foliar nutrient products. However, before tank mixing Enfold Insecticide use a jar test, as described below, to test the physical compatibility of Enfold Insecticide with tank mix partners.

1. Using a quart jar, add the proportionate amounts of the products to 1 qt. of water. Add wettable powders and water-dispersible granular products first, then liquid flowables, and emulsifiable concentrates last.
2. After thoroughly mixing, let the mixture stand for at least 5 minutes. If the combination remains mixed or can be remixed readily, it is physically compatible.
3. If compatibility is acceptable, follow the instructions in **Mixing Instructions: Enfold Insecticide Tank Mixtures**.

### **NOTE:**

- If using Enfold Insecticide in a tank mixture:
  - Do not mix with any product that prohibits such mixing.
  - Observe all directions for use, crop/sites, use rates, dilution ratios, precautions, and limitations that appear on the tank mix product label.
  - Do not exceed any labeled use rate.
  - Follow the most restrictive label precautions and limitations.
- Tank mixtures or other applications of products referenced on this label are permitted only in those states in which the referenced products are labeled.

### **Mixing Instructions: Enfold Insecticide Tank Mixtures**

1. Add 1/3 of the required amount of water to the mix tank.
2. Start the agitator running before adding any tank-mix partners.
3. When using Enfold Insecticide in tank mixtures:
  - a. All products in water-soluble packaging should be added to the tank before any other tank-mix partner, including Enfold Insecticide.
  - b. Allow the water-soluble packaging to completely dissolve and the product(s) to completely disperse before adding any other tank-mix partner to the tank.

- c. Then add other tank-mix partners in this order: wettable powders, wettable granules (dry flowables), liquid flowables, liquids and emulsifiable concentrates. Always allow each tank mix partner to become fully dispersed before adding the next product.
4. Provide sufficient agitation while adding the remainder of the water.
5. Maintain agitation until all the mixture has been applied.

---

## USE DIRECTIONS

---

- **Location Prohibition:** Do not use Enfold Insecticide in greenhouses.
- **Number of Applications:** Do not apply more than 3 sequential applications of Enfold Insecticide. Rotate to another insect control product with a different mode of action for at least two applications.
- **Adjuvant Recommendation:** Thorough spray coverage of plant foliage is essential for optimum control. To provide optimum coverage and insect control, the use of a penetrating type spray adjuvant such as horticultural spray oil (not a dormant oil) or a nonionic surfactant at the manufacturer's suggested rate is recommended. Do not use a sticker/binder type adjuvant or tank mix with products that contain a sticker/binder component in the formulation because this may reduce Enfold Insecticide insect control.
- **Application following failure of another insecticide:** Do not apply Enfold Insecticide following the failure of another product if the larvae are large (>1/4 inch long).

## Plant Safety

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>NOTICE TO USER:</b> Plant tolerance to Enfold Insecticide has been found to be acceptable for many genera and species. Due to the large number of species and varieties of ornamentals and nursery plants, it is impossible to test every one for tolerance to Enfold Insecticide. The professional user should determine if Enfold Insecticide can be used safely prior to commercial use. In a small area, test the recommended rates on a small number of plants for phytotoxicity prior to widespread use.</p> |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

**Tank Mixture:** The safety of all potential tank mixes on all plants may not have been tested. Before applying any tank mixture not specifically recommended on this label, the safety to the target plants should be confirmed.



| Pest                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | oz. Product/A per Application | Instructions                                                                                                                                                                                                    |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Beet armyworm<br>Cabbage looper<br>Cabbage webworm<br>Corn earworm<br>Cross-striped cabbageworm<br>Diamondback moth<br>Fall armyworm<br>Imported cabbageworm<br>Southern armyworm<br>Tobacco budworm<br>Tobacco hornworm<br>Tomato hornworm<br>Tomato fruitworm<br>Tomato pinworm<br>Yellowstriped armyworm                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 2.4-4.8 oz./A                 | Apply when larvae are first observed.<br>Application may be repeated at a 7- to 14-day interval to maintain control.<br><br>Use 2.4 oz./A for low to moderate infestations and 4.8 oz./A for high infestations. |
| Alfalfa looper<br>Apple pandemis<br>Bagworm<br>Bud moths:<br>eyespotted<br>tufted apple<br>Cabbage looper<br>Cankerworm species<br>Codling moth<br>Common winter moth<br>European winter moth<br>Fall webworm<br>Filbertworm<br>Fruitworms:<br>cherry<br>green species<br>laconobia<br>Genista caterpillar<br>Gypsy moth<br>Hickory shuckworm<br>Leafminers:<br>blister moth species<br>tentiform species<br>Leafrollers:<br>filbert<br>fruittree<br>obliquebanded<br>omnivorous<br>redbanded<br>variegated<br>Lesser appleworm<br>Liriomyza leafminers <sup>1</sup><br>Mimosa webworm<br>Navel orangeworm<br>Peach twig borer<br>Omnivorous leaftier<br>Orange tortrix<br>Oriental fruit moth<br>Pear psylla <sup>2</sup><br>Pecan bud moth<br>Pecan casebearer species | 3.2-4.8 oz./A                 | Apply when larvae are first observed.<br>Application may be repeated at a 7- to 14-day interval to maintain control.<br><br>Use 3.2 oz./A for low to moderate infestations and 4.8 oz./A for high infestations. |

|                                                                                                                                                                                         |  |  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|
| Pecan serpentine leafminer<br>Redhumped caterpillar<br>Soybean looper<br>Spider mites <sup>2,3</sup><br>Spruce budworm<br>Tent Caterpillars:<br>Eastern<br>Forest<br>Walnut caterpillar |  |  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|

<sup>1</sup> Enfold Insecticide provides suppression of *Liriomyza trifolii*, *Liriomyza sativae*, and *Liriomyza hudriobrensis* populations. Suppression means either erratic control ranging from good to poor or consistent control at a level below that which is generally considered acceptable for commercial control.

<sup>2</sup> Enfold Insecticide provides suppression. Suppression means either erratic control ranging from good to poor or consistent control at a level below that which is generally considered acceptable for commercial control.

<sup>3</sup> Refers to phytophagous mites in the Acari subfamily Tetranychinae.

### Use Restrictions

- Allow a minimum of 7 days between applications.
- Do not apply more than 28.8 oz./A per season.

## STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

### Pesticide Storage

Store in a cool, dry area under lock and key. Post as a pesticide storage area. Always store pesticides in the original container. Store away from food, pet food, feed, seed, fertilizers, and veterinary supplies. Place liquid formulations on lower shelves and dry formulations above.

### Pesticide Disposal

Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

### Container Handling

Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two



more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration.

---

Enfold™, the ALLIANCE FRAME, the SYNGENTA Logo and the PURPOSE ICON are Trademarks of a Syngenta Group Company

©2011 Syngenta

For non-emergency (e.g., current product information) call  
Syngenta Crop Protection at 1-800-334-9481.

Manufactured for:  
Syngenta Crop Protection, LLC  
P.O. Box 18300  
Greensboro, North Carolina 27419-8300

SCP

(Non-detachable Container Label)

**RESTRICTED USE PESTICIDE**

**TOXIC TO FISH, MAMMALS, AND AQUATIC ORGANISMS**

FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION.

Enfold™  
Insecticide

**GROUP 6 INSECTICIDE**

For control of listed lepidopterous larvae (worms/caterpillars) and suppression of leafminers and spider mites on outdoor-grown plants in commercial nursery production

|                                              |        |
|----------------------------------------------|--------|
| Active Ingredient:                           |        |
| Eamectin benzoate (CAS No. 155569-91-8)..... | 5.0%   |
| Other Ingredients:                           | 95.0%  |
| Total:                                       | 100.0% |

Enfold Insecticide is a soluble granule containing 5% eamectin benzoate.

**KEEP OUT OF REACH OF CHILDREN.**

**CAUTION**

See additional precautionary statements and directions for use in booklet.

**AGRICULTURAL USE REQUIREMENTS**

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. Refer to supplemental labeling under "Agricultural Use Requirements" in the Directions for Use section for information about this standard.

EPA Reg. No. 100-XXXX

EPA Est. XXXXX

Product of XXXXX  
Formulated in XXXXX

SCP

Net Weight



Refer to **FIRST AID** section in attached booklet for additional precautionary statements.

## **PRECAUTIONARY STATEMENTS**

### **Hazards to Humans and Domestic Animals**

#### **CAUTION**

Harmful if swallowed, inhaled, or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse. Avoid breathing dust or spray mist. Prolonged or frequently repeated exposure may cause allergic skin reactions in some individuals.

This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow drift to blooming crops or weeds if bees are visiting the treatment area.

#### **Physical or Chemical Hazards**

Do not use or store near heat or open flame.

## **STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage and disposal.

### **Pesticide Storage**

Store in a cool, dry area under lock and key. Post as a pesticide storage area. Always store pesticides in the original container. Store away from food, pet food, feed, seed, fertilizers, and veterinary supplies. Place liquid formulations on lower shelves and dry formulations above.

### **Pesticide Disposal**

Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

### **Container Handling**

Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow

begins to drip. Fill the container  $\frac{1}{4}$  full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration.

**Chemigation: Do not apply this product through any type of irrigation system.**

Enfold™ and the SYNGENTA Logo are Trademarks of a Syngenta Group Company.

©2011 Syngenta

Manufactured for:  
Syngenta Crop Protection, LLC  
P.O. Box 18300  
Greensboro, North Carolina 27419-8300

SCP

Enfold (draft new product) – pl – 5/13/11  
000100-XXXXX.20110516.ENFOLD\_NEW-PRODUCT\_MAY2011.pdf





Syngenta Crop Protection, LLC  
P.O. Box 18300  
Greensboro, NC 27419-8300

Tel. 336-632-7207  
Fax: 336-632-5688

tom.parshley@syngenta.com

**Fed Ex - E-Submission**

May 17, 2011

Document Processing Desk (E-SUB) (APPL) (REG-FEE)  
Office of Pesticide Program (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

**Attn: FRONT END SCREEN**

**SUBJECT: ELECTRONIC SUBMISSION ENCLOSED  
NEW PRODUCT APPLICATION:  
ENFOLD Insecticide  
EPA File Symbol No.: 100-XXXX**

Dear Front End Screen:

Syngenta Crop Protection, LLC herein respectfully submits a new product application via electronic submission. One (1) CD is enclosed, containing a WinZip file with one XML file and 16 PDF files of data volumes and required forms.

If you have any questions about the electronic package, please contact my Administrative Assistant, Pat Eay at 336-632-6746 or [pat.eay@syngenta.com](mailto:pat.eay@syngenta.com) and for e-submission technical questions, please contact Kimberly Clark at 336-632-2065 or by email at [kimberly.clark@syngenta.com](mailto:kimberly.clark@syngenta.com). All other regulatory correspondence should be addressed to Thomas J. Parshley via the contact information noted in the submission letter.

Kind Regards,

Thomas J. Parshley  
Sr. Regulatory Product Manager  
Professional Products – Lawn & Garden  
336-632-7207

E-SUBMISSION

443